20TH ANNIVERSARY
GREAT SPORTS LEGENDS DINNER

MIAMI PROJECT ACHIEVEMENTS
TOOLS OF TECHNOLOGY
My family and I welcome you to the inaugural issue of The Project magazine. I am sure you will agree that The Miami Project and its mission is better showcased in this new format. The Miami Project has sure come a long way! I remember back to the early days in 1985 and the promise my family made to me that nothing would stand in the way of getting me out of my chair. That promise has become the hope for the millions of people worldwide in wheelchairs to get up and walk again.

I have witnessed the transformation of the science from a once hopeful view to now one of reality through credible research. Cells and nerves that once lay dormant are now vibrant and robust with growth carrying the messages of progress through motor and sensory recovery. Stem cells shine a new light of discovery on an already bright horizon. We are leading the way in promoting clinical trials across the world to take advantage of the prospering evidence that the basic science can be transferred to humans. Our rehabilitative research team will continue to guide the spinal cord injured community to reach their full potential through exercise protocols.

When you come through the doors of The Miami Project, you immediately realize what it’s all about. I personally invite everyone to come experience a day at The Miami Project. You will see the dedication of the hundreds of scientists, technicians, and staff members working passionately because they know that the kind of time clock they are punching is the time clock that is ticking until we find a cure. Lastly, and as important, you will see the camaraderie of the spinal cord injured community as we gather daily at The Miami Project because we understand that The Miami Project is the only place where our hopes and dreams will be realized.

I want to thank all of our donors and friends who share our passion for a cure and the only way it will happen is through your continued support. Welcome again to The Project magazine. Enjoy.

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As The Miami Project celebrates its 20th year, I reflect back on the last 40 years of my journey and my commitment to improving the quality of life of patients with spinal cord injury and paralysis. While my early career involved basic science research, more recently most of my time and effort has a clinical focus including the medical and surgical management of patients with new injuries, neuroprotection, as well as treatment of long-term consequences of spinal cord injury.

Originally, my inspiration to become a neurological surgeon and to pursue a career directed to treatments of paralysis came from my observation of volunteers working in the laboratories of Dr. L.W. Freeman, a leader in spinal cord injury research. The volunteers in wheelchairs arrived daily into our laboratories full of enthusiasm for our work and with an extraordinarily positive outlook on life. Often, this was in spite of the fact that most of them were suffering with severe physical and psychological pain.

For the last 30 years I’ve had the privilege of treating thousands of spinal cord injury patients who have started out as my patients and later often became lifelong friends and supporters of our research efforts. Among them are Donald Misner and Beth Roscoe who were the earliest backers of our project. Now, because of the unwavering support of many and the truly significant advances in science, The Miami Project team is no longer asking if, but rather is now focusing on when.

It is truly thrilling for an old timer like me to be witnessing what I consider the “renaissance” of cellular therapies and transplantation. I am often accused of being a “Texan” because I state with confidence that The Miami Project is not only the largest, but the most credible and productive neuroscience research center in the world devoted to paralysis related issues.

On the occasion of The Miami Project’s 20th anniversary, I am reminded of a quote by the renowned rocket scientist Robert Goddard who said, “It is difficult to say what is impossible, for the dream of yesterday is the hope of today and the reality of tomorrow.” I believe this to be true and I would like to renew my vows and recommit myself totally towards expediting the work of our scientists and collaborators from around the world to give closure to our quest for effective treatments and a cure for paralysis.

Thank you for your support, friendship, and belief in our mission.

Barth A. Green, M.D., F.A.C.S.
Professor and Chairman
Department of Neurosurgery
Twenty years ago on a cold October day, Marc Buoniconti was playing football for the Citadel. Then came the tackle – a paralyzing tackle that forever changed Marc’s life and the lives of the Buoniconti family. That fateful date also changed the lives for millions of people who were or would one day become spinal cord injured.

At the hospital that night, Nick and Terry Buoniconti made a promise to their son that money would never stand in the way of finding a cure for paralysis. “For the first time in my life I couldn’t help my son,” said Nick Buoniconti. “I realized that there was nothing I could do to make him better. But I knew I could raise the money and awareness to at least give the scientists a chance to find this cure.” That promise would ultimately change the world.

On September 27, 2005, Nick Buoniconti continued to make good on his promise when the 20th Annual Great Sports Legends Dinner raised a record-setting four million dollars. That is the largest amount of money ever raised at a single spinal cord injury event in the world. Thirteen hundred people from the realms of business, entertainment, sports and philanthropy came together for this historic night. Because of The Miami Project and The Buoniconti Fund, two hundred million dollars have been directed to spinal cord injury research. Unbelievable!

What is more impressive is how far the scientific community has actually come in the past twenty years in finding a cure for paralysis.

Thirty-six centuries ago in ancient Egypt, in one of the oldest medical books ever discovered, a doctor describes a patient who fell and broke his neck. The doctor recognized that the injuries caused paralysis and stated that the ailment “was not to be treated.” Twenty years ago little, if anything, had changed in the way the scientific and medical community viewed paralysis.

The fact was, if you became spinal cord injured, you had no hope. If you were lucky, you had family who would take care of you. For many people, families were not able to handle the responsibility and care they needed, so they were taken to nursing homes or placed in a corner and hidden away from the public’s view.

In the mid 1980s, most doctors and scientists did not believe a cure was possible. Few even contemplated the notion that nerves could regenerate or even felt it worthwhile to actually study the central nervous system and investigate its possibilities.

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Unbelievable

How an injury changed the way we approach spinal cord research.

“Dr. Green put his professional reputation on the line for this cause” said Marc Buoniconti. “He endured international ridicule from peers at professional conferences and in major papers such as the Wall Street Journal.”

“I think one of the most difficult and painful things to hear from my colleagues was
The radical change in belief and more importantly the understanding that a cure for paralysis will be possible is a testament to how much The Miami Project and other scientists have changed history.

“The last two decades have taken us from the dark ages of spinal cord research to the initiation of clinical trials targeting paralysis,” says Miami Project Scientific Director W. Dalton Dietrich, Ph.D. “The Miami Project’s cutting edge research and holistic approach have provided many important pieces to this complicated puzzle of spinal cord injury and give us great optimism for the near future.”

Researchers now know that the adult central nervous system can be coaxed into regenerating. They’ve discovered that barriers to regeneration can be broken down and for the first time have demonstrated that nerve fibers can regrow beyond an area of injury.

“What is also impressive is the dramatic and enthusiastic increase in the number of young as well as established scientists entering the field of spinal cord injury research,” continues Dr. Dietrich. “From this enthusiasm, new research centers are being created all over the world. There is a synergy that will help find the cure for spinal cord injury.”

As a teenager, Marc Buoniconti was a handful. He had an attitude. He was all about football and fun. Marc ended up at The Citadel for a reason. Discipline. The person who enrolled in that military school is not the person he has become.

“It’s almost been an amazing experience for me to see myself transform over the years,” Marc says. “I look at the life I led before: football, not a care in the world, not a lot of direction, not a lot of charity. And now: being able to understand more of what life is about. It’s giving back. It’s trying to make a difference. It has been a crash course in humility. Being part of a life-changing organization, I feel my life is much more rewarding now than it ever was on my feet. To see the hope on people’s faces – I would never give any of that back.”

Twenty years and two hundred million dollars later, the Buoniconti’s and the more than fifty thousand donors have changed history. The Miami Project and the world are much closer to figuring out one of mankind’s greatest challenges – understanding how to repair the central nervous system and ultimately to cure paralysis.

“How many times does one get the chance to really, and I mean really, radically change history?” said Marc. “All the people who have ‘been there for us’ can know that they are a part of this miracle.”
Miami Project Scientific Achievements

The broad scope of research carried out at The Miami Project has focused on answering questions that help define human spinal cord injury and reveal strategies for the repair of damaged spinal tissue. The team has also made advances in knowledge that have improved the current care of people with SCI. Over the last two decades, The Miami Project has made claim to several scientific achievements.

- **Pioneered** the concept of a multidisciplinary approached to SCI research; assembled the most comprehensive team of researchers to address the multifaceted problems of spinal cord injury.

- **First** to build a state-of-the-art SCI research facility that under one roof houses the tools and technology that in the hands of researchers will provide advances to find a cure.

- **Established** the largest collection of postmortem human spinal cord tissue in the Western Hemisphere. Pioneering anatomical observations and physiological recordings have revolutionized the understanding of human injury.

- **Designed** novel experimental strategies including mild lowering of body temperature (hypothermia) to limit secondary damage following SCI. Promising effects with Interleukin-10, and the inactivation of NFkappaB are also under investigation.

- **First** to demonstrate that adult human central nervous system neurons can regenerate when provided with a supportive cellular environment.

- **Discovered** that the adult nervous system has a remarkable capacity to accept and integrate transplants of neuronal cell lines. Demonstrated that embryonic neurons can reconnect to muscle and restore its function in animals.

- **Initiated** studies to explore whether neural precursor cells or stem cells can be developed and stimulated to mature into different types of nervous system cells.

- **First** to establish optimal laboratory methods to isolate and expand human Schwann cells in culture from adult peripheral nerves – which represent critical steps for the use of autologous Schwann cells grafts for neural repair.

- **First** to demonstrate remarkable improvement in walking function in animals using an innovative treatment that combined Schwann cell grafts with the administration of a cell messenger molecule (cyclic AMP) and the drug, rolipram.

- **First** to conceive and develop a novel intraoperative monitoring technique that makes spine surgery safer. The technique is now used nation-wide and reduces the risk of paralysis during pedicle screw placement surgery.

- **First** to provide evidence that humans possess specialized nerve circuitry that influences walking and could possibly be enhanced by rehabilitation training. These observations contributed to the development of body weight support gait training. Miami Project investigators are currently adding to the body of knowledge regarding the effectiveness of this rehabilitative training.

- **First** to show that grip strength and sensory/motor function can be improved in people with chronic SCI by using a task-practice based therapy that influences the neural circuitry for controlling arms and hands.

- **Completed** extensive testing of a computer-driven Parastep® 1 assisted-walking system. Showed its ability to enhance cardiovascular and conditioning effects and provided supporting evidence for approval by Medicare to reimburse for the device.

- **Provided** evidence that electrically-stimulated exercise positively influences cardiopulmonary function and strengthens the immune system in paralyzed people.

- **First** to offer proof that poor sperm motility in men with SCI is a result of organ dysfunction. New knowledge and assistive reproductive procedures have afforded the opportunity for men with SCI to father biological children. Recent Miami Project findings reveal the possibility of a rational treatment for the infertility.

- **Created** bioengineered cell line transplants that show promise in the treatment of chronic SCI pain.

- **Developed** new strategies for the multidisciplinary evaluation of SCI pain. The comprehensive state-of-the-art approach targets pathological, physiological, psychological and social aspects of pain in order to tailor individual treatment strategies. This combination of methods will be useful in evaluating the outcomes of spinal cord injury clinical trials.
Despite the many advances in spinal cord injury research, it is still a permanent, life-altering trauma for most people. Each year, a hundred or more research subjects join clinical studies at The Miami Project to Cure Paralysis hoping to help researchers find more treatments and better therapies for spinal cord injuries. Here is the story of one research volunteer.

Jane Olufsen did not answer the phone the first time it rang on April 19, 2000. It was 11 p.m. in Houston, Texas, she was already in bed, and she assumed it was one of her teenaged son’s friends calling to get him up.

But when the phone rang yet again, she finally answered. It was her 18-year-old son Erik’s college roommate. “He said, ‘Are you coming to the hospital?’ and I said, ‘What?’”

The roommate realized she had no idea why he was calling.

“Erik fell,” he said. “I think he’s broken his neck.”

Still, all Jane could manage was a terse “OK.”

To which Erik’s friend responded, “He’s paralyzed.”

With that phone call, the Olufsen family’s world—their friends, their home, their interests, their passions, their politics, their questions, their future—underwent a seismic shock. It would never be the same again.

He Knew He Was In Trouble

Four hours away, in Waco, Erik Olufsen was being rushed to an emergency room.

It was a warm spring night, a few days before Erik’s 19th birthday, and he had gone to a party with his friends—a typical college party. But Erik did something that was not so typical for him. As he was leaving, he decided to show off by dancing on the railing of the stairs.

When he slipped, the fall was not far, but his head landed at an angle that shattered one of his cervical vertebrae. He was unconscious for a short time, and when he came to, he wasn’t in any pain. So there was no sense of urgency or panic.

“Come on, Erik, get up,” his friends said. And then he realized he couldn’t move.

Everything slowed down for Erik, moving in and out of focus as the shock of his injury began to overtake his body. He recalls bits and pieces of the first few hours: “Here is something odd that I remember from that night—I was wearing a new pair of shorts, and I remember that they [emergency medics] asked me if they could cut them off. I was surprised by that question.
considering my situation, and I thought it was very nice of them to ask. The thought crossed my mind to say no, these are brand new shorts, but I knew I was in some serious trouble and told them yes. I also remember telling them not to throw out the shorts, because I had a big $7 in my wallet.”

Shock and Horror
The first indication of Erik’s condition came when Jane walked into the hospital and saw dozens of college students praying on the floor of the waiting room. It was not the most comforting sign. “I stepped over all of them and went into the emergency room,” she recalls.

When she reached her son, it took all her strength not to panic. She hadn’t been able to tell how seriously he was hurt from the phone calls she had made. She was hoping—planning—that Erik’s injuries were not as bad as they sounded. Then she saw him.

“Physically Erik looked the same as ever. He was still in the body that was normal just hours earlier. But he was laid out like he was dead, completely motionless,” Jane recalls. “From his shoulders to his heels, he was cemented to the bed. When I touched him, he was dead weight.”

“All the apparatus attached to him looked like a sci-fi movie or a movie about a torture chamber. He was so scared. How would you feel if you were at a friend’s house and then within an hour you are paralyzed with all kinds of equipment hooked up to you, people in your room crying and a priest praying over you?”

“If I fell apart, that would scare him even more. I had to find one little thing to make it better—so I did not cry when I was in the ICU with him.”

While his mother was driving to Waco, physicians had been busy trying to figure out the extent of Erik’s injuries. His fall had shattered the sixth of seven cervical vertebrae, more commonly referred to as C6. The location of one’s injury is what determines whether the arms and legs or only the legs will lose function.

By the time Jane had arrived at the hospital, the surgeons were ready to stabilize the injury, but there was no way of knowing how bad it would turn out to be.

Once, He Knew Where He Was Going
Erik seemed an unlikely person to end up in this situation. He was thoughtful, mature and responsible, his parents said, and he knew where he was going in life. “I had my heart and life right on schedule,” Erik says.

In the aviation science program at Baylor College, Erik had enough credits to be nearly one year ahead of his class. With ten more hours of flight time (about two weeks of training), he would have his flight instructor license and would start teaching new students how to fly. Then he had “a bad night. And it’s been a long hangover,” he says.

Erik hates to talk about how he was injured. But he goes over and over that night and wonders how it happened. “Every day I get up and I see my wheelchair,” he says. “It’s a reminder of my stupidity.”

Three days after the accident, Erik underwent surgery while still completely paralyzed. As the weeks passed, Erik began regaining feeling and movement fairly quickly. He became convinced that this was only a temporary state, that maybe he would be in a wheelchair for a year and then he’d be better. His parents felt the same way. “How do they know he won’t get better?” Jane remembers thinking.

Life for the Olufsens was now filled with a search for treatments and techniques, leading Erik to participate in two clinical trials in Houston. Jane became a self-
taught expert, not only well-versed in the literature, but also criss-crossing the country using plane tickets provided to her pilot husband to attend SCI lectures, conferences and fund-raisers.

Jane heard Barth Green, M.D., professor and chairman of the Department of Neurological Surgery and founder of The Miami Project, speak at one of those conferences. Green has been unequivocal in his belief that the time has come for a breakthrough in SCI research: “Our laboratories continue to produce significant advances in the field. These are important pieces of the puzzle for The Miami Project and our efforts to find a cure for paralysis. We feel each step represents real hope for moving our science closer to the clinic,” says Green. “Since we started 20 years ago, I have seen small steps turn to strides and that fuels my enthusiasm that we are getting closer each day to our goal of finding a cure.”

Jane and Erik then read about the breakthrough The Miami Project announced last year of a new triple-combination strategy that enabled injured rats to regain up to 70 percent of their walking ability. And when The Miami Project announced it was recruiting volunteers for a clinical study run by Dr. Edelle Field-Fote beginning in January, Erik and Jane loaded up their car and moved to Miami for three months.

Do The Locomotion
One critical component of recovery after SCI is rehabilitation. Now in the third year of a five-year study entitled “Comparison of Locomotor Training Techniques for Individuals with Chronic Incomplete Spinal Cord Injury,” Field-Fote is investigating several different training methods to see if one technique may have a better outcome in helping patients walk. Thirty-four SCI individuals from across the country have come to Miami to take part in these studies, the largest of which will be completed in 2007.

Field-Fote examined Erik and determined that four years after his injury, “he has some sensation and he has some movement, but the majority of the muscles below the level of injury are not able to move against gravity.”

Here is what Erik can and cannot do: He has movement in his arms, but no fine motor skills due to loss of control of his hands and fingers. He can stand. He can take a few steps with braces on his legs, but spasms overtake his mobility to the point that he needs the wheelchair for transportation. He can feel, but he can’t feel hot or cold. He can dress himself, but he has trouble pulling on his socks. He can use a pen, but he can’t open a can of soda or put a plug into an outlet.

Erik graduated from college on schedule but has had to give up his dream of being a pilot. He can drive, but he had to lie in a ditch for close to an hour after a car accident until someone could help him move. “People say, even though you’re disabled, you can do anything if you put your mind to it. But you can’t,” says Jane. Erik cannot even become an air traffic controller because the medication that suppresses his spasms is banned by the Federal Aviation Administration.

In Field-Fote’s study, four groups are undergoing different training techniques, all of which incorporate the use of partial body weight support to relieve some of the weight on the legs. “One of the groups is training on the treadmill with one therapist moving each leg,” Field-Fote says. “The other group is training on the treadmill with stimulation to move their legs. Another group is training on the treadmill with the robot to move their legs. And the fourth group is training overground with stimulators on their legs. We call them treadmill manual, treadmill stem, robot and overground.”

Erik has been assigned to the treadmill manual group. To say it is a struggle for him to walk is an understatement. His attempts to walk are a battle, his long thin legs like Don Quixote’s lances tilting at windmills. He throws his entire body into the fight, using every ounce of effort, every weapon he has. It’s not pretty. And it’s not enough.

Over the course of an hour, Erik’s trainers use all of their physical strength to try to get his feet to move when he walks. The training stops when his feet just won’t land straight or a spasm comes over him, and then restarts when he’s rested a bit. He does this five days a week.
Just as he focused on his flight training before he was injured, Erik has now redirected his energy to overcoming his disability. But SCI patients must be so much more vigilant and attuned to their body’s weaknesses than the non-injured are. One day, Erik arrives with an abrasion on his leg. As he was exercising the night before, his leg was rubbing against the side of the wheelchair but he never felt it. And under a thick thatch of strawberry blond hair on the back of Erik’s head is a saucer-sized bald spot, caused by a pressure sore a few weeks after his injury. It is a common mode of injury for SCI patients, and these injuries can quickly deteriorate into life-threatening conditions.

Spinal Cord Injury Research Advances
When actor Christopher Reeve was paralyzed in a horseback riding accident, the plight of those with SCIs was illuminated for many people. His high public profile enabled him to draw unprecedented attention and funds for SCI research, including the work being done at The Miami Project to Cure Paralysis.

At the same time of the increased focus on SCI came significant advances in the field. Researchers now believe that a cure for paralysis is coming—and soon. But it’s going to take a lot more money and a lot more research. A combination of basic research discoveries together with new surgical techniques, new rehabilitation strategies and new pharmaceuticals will be the only way to heal the multitude of damages suffered in a spinal cord injury.

The vast majority of these patients will not get better on their own. There have been some miraculous recoveries from spinal cord injuries, but most patients won’t see miracles—they need medicine. Clinical research and advances in the field are now enabling patients to live longer, avoid many of the complications that were life-threatening, and regain some normality in their lives.

“These are exciting times in the area of spinal cord injury research, and recent discoveries in the area of axonal regeneration will greatly aid in the translation of experimental findings into the clinic,” says W. Dalton Dietrich III, Ph.D., scientific director of The Miami Project. “Guidelines for clinical trials and safety studies are being discussed and optimism is high in regards to reaching our ultimate goal of improving function in people with spinal cord injury.”

In the five years since their son was injured, Erik’s parents have become fervent supporters of research and more and more convinced that a cure is coming. “I feel that SCI is like a wheel, with spokes coming out in all directions, and The Miami Project is the center of the wheel,” says Erik’s father, Niels. “If a cure is going to come, it’s going to come out of here.”

Erik is still the conscientious, good-natured young man he was before his accident, so he is going to work hard at recovering function. He does not want to wallow in the past, and he doesn’t want to complain about his plight. And he still feels he’s going to get better, but “I spent the first three years convinced I was going to walk. Now I don’t put a time frame on it.”

By Robin Nissim, editor of Miami Medicine
Photos by Donna Victor

Editor’s note: Potential volunteers for Dr. Field-Fote’s study are those who have an incomplete injury above T10 and who have an ability to stand and bear weight without braces.
What do golfing icon Jack Nicklaus, Oscar award winning actor Tommy Lee Jones and sportscasting legend Bob Costas have in common? These high-profile individuals were honored at the 20th Annual Great Sports Legends Dinner at New York’s historic Waldorf=Astoria hotel. Not only was the event sold out but the grand affair raised more than $3.2 million. Supporters Martin and Barbara Zweig were so moved by the evening they donated an additional $1 million to the cause.

Over the years, The Buoniconti Fund has honored individuals from the sports, business and entertainment industries who have made a difference in our world including Michael Jordan, Wayne Gretzky, Muhammad Ali, Mickey Mantle, Dan Marino, Greg Norman,
Gloria Estefan, Walter Cronkite, Chris Evert, Mia Hamm and more than 200 others.

This year’s Great Sports Legends and honorees were: Tony Dorsett, Ray Bourque, Bob Costas, Ozzie Smith, Lenny Wilkens, Hal Sutton, Mike Richter, K.C. Jones, Gary Hall Jr., Don Garlits and Phil Mahre. Golfing legend, Jack Nicklaus was honored with the Buoniconti Fund Humanitarian Award. Oscar Award Winning Actor, Tommy Lee Jones was given the Outstanding Philanthropist award and the Founder of Outback Steakhouse, Tim Gannon, was given the Charitable Business Leader Award. NBC’s Tom Brokaw served as our master of ceremonies for the fourth year.

“Celebrating our 20th anniversary is significant because the reality of a cure and implementing the technology we’ve developed is finally on the horizon,” said Nick Buoniconti. “We are changing the way the world looks at paralysis and we never could have accomplished this without the unwavering support of The Buoniconti Fund Board and our special friends.” For the past 20 years, the Great Sports Legends Dinner has raised more than twenty seven million dollars.
The past 20 years have taken us from the dark ages of spinal cord research to the initiation of clinical trials targeting paralysis. Cutting edge research has provided Miami Project scientists with new knowledge regarding why spinal cord neurons die after injury and has provided new hope for the acutely injured individual. Injury mechanisms that lead to delayed cell death are also being targeted for new drug development and neuroprotective strategies.

In the area of spinal cord injury repair, researchers have discovered ways to alter the spinal cord environment to enhance axonal regeneration and improve functional recovery. Inhibitory barriers to axonal growth have been broken down, and long tract regeneration has been documented for the first time. Novel strategies for applying growth-promoting factors through gene therapy have also increased our capacity to induce restorative processes.

Building on exciting breakthrough findings from last year that reported remarkable improvement in motor function in injured animals using a new combination therapy, researchers are now targeting chronic injury in hopes of one day treating individuals with chronic spinal cord injury.

In spinal cord injured subjects, rehabilitation strategies have already improved quality of life and enhanced function through locomotive training. Our synergistic approach to spinal cord injury has provided many important answers to this complicated puzzle of spinal cord injury and has given us great optimism for the near future.

A new generation of internationally respected neuroscientists trained by Miami Project researchers are, today, making important contributions to spinal cord injury research. We are extremely proud of our continuing progress and thank the many individuals who have helped to advance our cause and have brought us closer to a cure for paralysis.

W. Dalton Dietrich, III, Ph.D.
Scientific Director
The Miami Project to Cure Paralysis
Clinicians in various countries have initiated clinical procedures that involve the transplantation of what are claimed to be olfactory ensheathing cells (OECs) into people with spinal cord injury (SCI). Of interest has been the activity of Dr. Hongyun Huang in Beijing, China. Dr. Huang has implanted cells derived from human fetal olfactory bulb into more than 400 people with SCI who, after the procedures, report they have improvements in sensory and motor function within days. These anecdotal reports lead to questions such as: What degree of improvement is seen and are the gains maintained over time? Are there immediate or long-term risks to the procedure?

In an effort to obtain a fuller understanding of the potential benefits of Dr. Huang’s treatment, The Miami Project sent two scientists/clinicians to Beijing to observe the procedure and obtain first-hand information. Over a ten-day period in July 2004, Drs. James Guest and Tian Qian observed twelve patients, evaluating six of them for neurological function before and after surgery. While they had full access to patients, they were not permitted access to the cell preparation facility. Therefore, the investigators were unable to evaluate the standards by which the cells were being prepared.

Since returning from China, the researchers have published a peer-reviewed case study on one of the patients observed during their visit. That patient did experience some neurologic recovery within a few days of the cell implantation although he also experienced an episode of meningitis. Subsequently, Dr. Guest has also collaborated with researchers in Los Angeles and Switzerland to study other people who have since received the treatment. In their examination of seven patients before transplantation and for up to six months after, they observed minimal changes in neurological recovery. Of particular note is the observation that five of the seven patients experienced complications. Several had a meningitis-like reaction.

“It concerns me that more than half of the patients in this series of seven patients had some form of complication with little improvement in neurological function. I’m not convinced that the minimal recovery of function outweighs the risks of this procedure for most patients.”

In contrast to the way OEC transplants have been studied in China, Australian researchers have been carrying out a more limited but carefully-designed phase I clinical trial to evaluate the transplantation of cells, presumably OECs, which are obtained from biopsies of the patient’s own nasal passages.

Recently, the researchers based in Brisbane, Australia reported preliminary results in three study patients. One year after transplantation, the patients had no medical, surgical or other complications and the researchers conclude that their method for transplantation of OECs is feasible and safe. They plan to continue collecting data for three years to confirm the safety of the procedure over a longer time period. This long term follow-up will also provide information about whether the patients who received transplants have improved function compared to the control group, the patients in the study who did not receive the transplants.
Paralysis after spinal cord injury is due in part to the loss of myelin or the insulation around nerve fibers. One question that researchers have is – if new myelin can be formed in the spinal cord, can damage be reversed and function restored?

To date, the best evidence that remyelination can be achieved was reported recently by research colleagues at the University of Louisville in Kentucky and The Miami Project. Dr. Scott Whittemore, scientific director of the Kentucky Spinal Cord Injury Research Center and former principal investigator at The Miami Project, and Dr. Qilin Cao were lead researchers in the study that tested the use of partially differentiated stem cells combined with a gene therapy in paralyzed rats. Miami Project investigators Drs. Pantelis Tsoufas, Patrick Wood and Mary Bartlett Bunge were among Whittemore’s collaborators.

“Many other investigators have suggested that remyelination is a possible approach to repair the spinal cord, but this is the first study to show unequivocally that it works,” said Dr. Whittemore.

In the study, the researchers took special cells called glial-restricted precursors from the spinal cords of embryonic rats. Derived from stem cells, these precursor cells are specialized so they form only two kinds of cells: astrocytes, which help support neurons and influence their activity, and oligodendrocytes, which produce myelin. Since the scientists were interested in producing cells that would make myelin, they then used a modified virus to insert a gene call D15A into the precursor cells. This gene produces a protein that acts like the growth factors neurotrophin 3 (NT3) and brain-derived neurotrophic factor (BDNF). Both NT3 and BDNF help the cells that produce myelin (oligodendrocytes) to develop and survive.

When the treated precursor cells were injected into the injured spinal cords of rats, the investigators saw an improvement in the rats’ ability to walk. They also noted that some nerve fibers appeared to function as they were able to conduct electrical activity. Additionally, when they studied the spinal cord tissue after the combined treatment, they found that many of the transplanted cells survived and that about 30 percent of them developed into myelin-producing oligodendrocytes.

This treatment clearly promoted the formation of new myelin around nerve fibers in the damaged spinal cords of rats. The findings further demonstrate the promise of combination treatments and collaboration.

“This is one of a series of new studies showing that a combination of therapies is needed for successful spinal repair, in this case, specialized cells and growth factors. The experiments used a combination of outcomes — physiology, behavior, and anatomy — to point clearly at myelination as the cause for improved function,” says Naomi Kleitman, Ph.D., the NINDS program director for the grants that funded this work. “The study also is a good example of strong collaboration between two spinal cord injury research centers.”
The Tools of Technology

As scientists learn more of the mysteries of the human nervous system, they discover there is much more to learn. For example, now that it's known that spinal cord nerves can be enticed to regrow, new questions arise about how growing axons might actually find their connections.

"Scientists are largely driven by wanting to know the answers. We just want to know stuff," says Dr. John Bixby, Miami Project principal investigator. "But we also want to know stuff that's useful. If you can pursue your thirst for fundamental knowledge and at the same time have it be useful, that's quite a combination."

Bixby, an established scientist who joined The Miami Project just two years ago, was a basic scientist who for many years had little concept of how his neurobiology research could actually be applied in medical treatments. That concept has changed though because of advances in knowledge of the nervous system but also because new cutting-edge technology is dramatically accelerating the search for treatments to regenerate damaged nerves.

Bixby and co-investigator Vance Lemmon, Ph.D. oversee The Miami Project's state-of-the-art High Content Screening Core Facility that houses new and sophisticated equipment. Acquired through the generous support of Diana and Joel Steinger, the equipment gathers and analyzes a huge amount of information. Scientists realize that to find molecules, genes or chemicals that could be vital to axon regrowth, they might need to investigate tens of thousands of molecules. That kind of exhaustive research would require far more time and personnel than anyone is willing to commit.

The impact that new technology has had or will have on spinal cord injury research cannot be overestimated. "Ten years ago, I thought it was crazy. I thought it was too difficult to do," says Lemmon in reference to the task of weeding through vast numbers of molecules to find one or two that could be useful. "Not anymore. High content screening has taken years off the process," he adds. "Smaller and smaller groups of people can work on bigger projects."

Bixby's and Lemmon's initial studies using high content screening have already uncovered four compounds from a library of 4000. These compounds clearly enhance axon growth in lab dishes and are currently under more critical review in animal studies. Recently, thanks to new funding from the United States Army, The Miami Project has embarked on a bigger high content screening project. The new project, which has five specific aims, is expected to help identify novel strategies to reduce nerve cell death and improve axon regeneration.

You might ask, "Why the Army?" Spinal cord injuries are a real and constant danger to active duty military personnel. Currently, there are no effective early treatments that could prevent the damage and promote recovery during the hours and days after an injury. The Army's funding will support research that utilizes this state-of-the-art screening technology that could ultimately lead to the identification of new treatments to protect soldiers and civilians immediately after injury and that promote recovery of function after SCI.

Announcements

Lynn Usher, Ph.D., postdoctoral fellow in the laboratory of Dr. John Bixby was one of four recipients of the 2005 BioFlorida's Legacy in Life Science Awards. The award recognizes outstanding research conducted in the biosciences by postdoctoral fellows working at Florida-based institutions and was underwritten by Nabi Biopharmaceuticals. In addition to the Life Science Award, Dr. Usher also receives postdoctoral fellowship funding from the Paralyzed Veterans of America. The two awards support Usher's research directed at identifying novel compounds that neutralize inhibitory molecules in the injured central nervous system environment and promote axon growth.

Research Associate Professor Ian D. Hentall, Ph.D. recently joined The Miami Project team to pursue investigations on pain and motor circuits in spinal cord injury. Formally an associate professor of physiology in the Department of Biomedical Sciences at the University of Illinois College of Medicine, Dr. Hentall has had previous collaborations with Miami Project scientists, Drs. Jacqueline Sagen and Brian Noga. As a neurophysiologist, his role at The Miami Project will include providing neurophysiological studies for other researchers who have developed promising interventions for treating spinal cord injury.
Combination Strategies for Repair

To regenerate successfully, axons are up against a number of obstacles. If they survive the injury, they must overcome an inhibitory environment, grow across the injury area, and re-enter the spinal cord on the other side of the injury for a chance to make connections with neurons involved in motor function. Therefore, treatments must be directed at helping regenerating axons overcome these obstacles.

A number of therapies by themselves have been shown to reduce inhibition, support growth and enhance re-enter of fibers. In the search for more effective treatments, scientists are demonstrating the potential benefits of combining two or more therapies. Last year, Drs. Mary Bartlett Bunge and Damien Pearse combined drugs with Schwann cell transplantation to enhance walking function in rats. This year, in the quest for optimal combination strategies, Miami Project scientists continued to test the interaction of Schwann cell transplants with other established experimental treatments.

Another Combination
Drs. Pearse and Bunge in collaboration with Canadian and Swiss investigators combined Schwann cell bridges with olfactory ensheathing glia (OEG) and an anti-inhibitory agent, chondroitinase ABC (cABC). Previous research results have shown that transplantation of OEGs enables regenerating axons to re-enter the spinal cord. cABC has also been shown to enhance regeneration by destroying inhibitory factors present in the glial scar. In their study, in rats with complete transection of the spinal cord, OEGs were injected above and below the cut spinal cord. After placing a synthetic guidance channel in the gap, Schwann cells were injected into the channel. Additionally, cABC was delivered every other day at each end of the channel via an infusion pump. The results revealed that some axons were able to grow through and re-enter the spinal cord on the other side of the injury. The rats also showed significant improvements in walking function. These results clearly demonstrated that grafts consisting of Schwann cells and OEGs combined with the application of cABC have additive effects.

Chronic Injury
As research studies help to understand the effectiveness of various treatments, a major goal is the development of therapies that will enhance recovery in people with chronic SCI and various levels of injury. This year, Miami Project scientists also report their findings in experiments that were designed to more closely mimic what is seen in human injury. Cervical injury may respond differently to repair strategies because of the difference in the size of the spinal cord and the distance the injury is from the brain. To evaluate neuroprotective and regenerative strategies in cervical injury, Drs. Pearse and W. Dalton Dietrich developed and characterized a cervical injury in rats. Further preclinical research can now take place in this injury model to determine if current treatment strategies work better in a cervical injury.

Understanding the effectiveness of new treatment strategies in chronic injury and knowing whether transplanted cells will survive for long period of time is also very important. To address the issue of chronic injury and survival of cells, Drs. Pearse and Bunge transplanted Schwann cells or OEGs in rats with contusion injuries suffered two month earlier. In this study, they found that 17% of the Schwann cells survived while only 2% of the OEGs survived. They also found the animals treated with Schwann cells showed improved motor function.

Promoting Health

Many studies report that people with chronic spinal cord injury are prone to abnormal levels of certain cholesterol fractions. These abnormal lipid levels may explain the occurrence of early heart and vascular disease after SCI. While explanations for this abnormality are still under investigation, poor diet and physical inactivity are likely explanations. To improve the cholesterol levels of people with SCI, increasing exercise and improving diet are highly recommended but may not be enough. It may be necessary to add drug treatments, however, little is known about which drugs are most effective in managing the lipid profiles of people with SCI.

This past year, Dr. Mark Nash reported results of a case study in which a common cholesterol lowering drug, Lipitor, was used to treat a 69 year old man with a cervical spinal cord injury. While the Lipitor did lower the so-called bad (or LDL) cholesterol, it also lowered the good (HDL) cholesterol. These effects did not change the risk for cardiovascular disease in this individual, as the ratio between the good and bad cholesterol remained unchanged. In another study, Dr. Nash reported evidence that paraplegics do not breakdown the fats and clear them from their systems as quickly as persons without disability. This delay in metabolizing fats has never before been reported, and may represent a significant risk for cardiovascular disease in people with SCI. Together, these findings point to the need for further research to understand the increased risk of cardiovascular disease and determine the best drugs therapies.
Philanthropy

In the world of spinal cord injury research, the word “GENEROSITY” usually signifies the dedication of private donors to accelerating the search for a cure for paralysis. Lois Pope, one of America’s leading philanthropists, gave the word “GENEROSITY” new meaning when she gave $10 million to the University of Miami to benefit The Miami Project to Cure Paralysis. Nick Buoniconti stated “a great moment in the history of The Miami Project was when Lois Pope made her incredible donation – the largest private gift of its kind to benefit spinal cord injury research. In recognition of Mrs. Pope’s outstanding philanthropy, the home of The Miami Project to Cure Paralysis is named The Lois Pope LIFE Center. Mrs. Pope is the founder of Leaders in Furthering Education (LIFE) and the Lois Pope LIFE Foundation. These two charitable organizations are devoted to saving lives, helping people help themselves, improving the quality of life for families in need and encouraging young Americans to become leaders by helping others. The organizations provide awards for medical research, scholarships, summer camp programs and much more.

Mrs. Pope started the Disabled Veterans’ LIFE Memorial Foundation, which is leading a successful drive to erect the first memorial in Washington, D.C. honoring America’s disabled veterans, the unsung heroes. Mrs. Pope is an active member of the University of Miami Board of Trustees and serves on innumerable medical research committees including the University’s Deans Leadership Cabinet. Her experience and generosity are legendary and her support is sought after by all.

For her exceptional humanitarian and philanthropic efforts, Mrs. Pope is the recipient of numerous awards, including the Timothy J. Nugent Award for outstanding individuals who have significantly influenced the spinal cord injured community of America. Mrs. Pope also has received the Health Care Heroes Award from the Greater Miami Chamber of Commerce, the VFW James E. Van Zandt Citizenship Award, the Ellis Island Medal of Honor and the Florida Women of Achievement Award. Mrs. Pope was also named a Daily Point of Light winner, an award inaugurated by former President George Bush to stimulate community service throughout the country.

Lois is the widow of Generoso Pope Jr., founder of The National Enquirer, where she served as art director. Born Lois Berrodin in Philadelphia, she resides in Delray Beach, Florida and Snowmass Village, Colorado. Lois has four children and several grandchildren and has successfully completed five New York City marathons. A truly diversified and amazing woman.

Needless to say The Miami Project is blessed to call Lois Pope a friend, benefactor and educated donor who lives to improve the lives of others. Lois Pope has been a loyal supporter of The Miami Project since 1994. In total she has given more than twelve million dollars to the University of Miami and continues her support.

The Miami Project honors Lois Pope for the healing and upliftment which she has fostered through her selfless giving.
“A woman beyond compare – someone who has dedicated her entire life to improving health, education, and welfare for the people of Florida and around the world.”

Christine E. Lynn

Nick Buoniconti calls her a “superstar”. Dr. Barth Green calls her “a woman beyond compare - someone who has dedicated her entire life to improving health, education, and welfare for the people of Florida and around the world.” Marc Buoniconti humbly said “thank you” as The Miami Project received yet another incredible donation from longtime supporter and South Florida philanthropist, Christine E. Lynn. Her latest gift of an additional $1,000,000 has established The Fund for Human Clinical Trials for Spinal Cord Injured Individuals. This generous donation will take clinical research at The Miami Project to the next plateau and set the stage for the additional cutting edge research that Mrs. Lynn supports.

Christine and her late husband, Eugene, are renowned for their generous contributions and remarkable knowledge of the medical arena and its philanthropic needs. Together, they have supported many programs within medical, and educational institutions all over the world. Their first donation to The Miami Project was dedicating the nationally recognized award winning lobby in the Lois Pope LIFE Center, home of The Miami Project. Continuing in her husband’s footsteps, Mrs. Lynn has endowed the Christine E. Lynn Distinguished Chair to honor Barth A. Green, M.D., Co-Founder and President of The Miami Project. “I have always admired Dr. Green’s dedication to his patients and to his research to find a cure for paralysis due to spinal cord injury,” said Mrs. Lynn.

As a gesture of respect and support for her lifetime dedication to SCI research, Dr. Green transferred his distinguished chair to Mary Bartlett Bunge, Ph.D. who is highly regarded for her work in regeneration. Dr. Bunge is known as the Christine E. Lynn Distinguished Professor of Neuroscience at The Miami Project to Cure Paralysis and the income generated from this incredible gift funds spinal cord regeneration research in her laboratory.

Christine E. Lynn has received numerous awards including the Soroptomist International 2001 Woman of Distinction Award, American College of Dublin International Humanitarian Award, Lynn University's Presidents Medal, University of Miami Gables Society Induction, Christian Humanitarian Service Honorary Doctorate of Divinity Degree, the Rotary International Outstanding Philanthropic Award for Leadership, Stetson University Philanthropy Award, The Women’s Guild of The Miami Project Ann Bishop Spirit of Excellence Award and the National Jewish Medical and Research Center Humanitarian Award.

Christine has truly changed the world for the better. Her incredible grace and style set the bar for the next generation of donors. She has created a lasting legacy knowing that these gifts will significantly advance progress in research that will lead to better treatments and eventually a cure for those with spinal cord injury. On behalf of the spinal cord injury community, The Miami Project salutes Christine Lynn for the healing and upliftment of humanity which she has fostered through her selfless giving.
Craig H. Neilsen and Ameristar Casinos Raise $777,000

Craig H. Neilsen, founder of The Craig H. Neilsen Foundation and Chairman and CEO of Ameristar Casinos, is a man of vision and an inspiration to all who know him. His personal story is one of tragedy, triumph and inspiration.

One snowy night in early November of 1985, Craig was involved in a serious car crash that left him paralyzed. Through his determination and inner strength, Craig has proven that life does not end after a spinal cord injury and has become a successful businessman in real estate development, construction and gaming.

After Craig Neilsen’s injury, his involvement in his companies remained steadfast. In 1993, Craig established Ameristar Casinos. Through his leadership and guidance, Ameristar has invested more than $1.55 billion in the development and expansion of eight properties since 1996. Each Ameristar-branded property holds the leading share in its local market.

Craig’s real estate and development company, Neilsen & Company, is currently developing a $60 million commercial project along the majestic rim of the 500-foot Snake River Canyon in Twin Falls, Idaho.

In recognition of his personal accomplishments, Craig was recognized as the “Best Performing CEO” by the American Gaming Association in 2002. Most recently, Craig was inducted into the American Gaming Association’s 2005 Hall of Fame.

Even before establishing The Craig H. Neilsen Foundation, Craig has had a long-standing history of commitment to giving back to those in need. Craig’s generosity, matched by that of his company was evident once again as his foundation held its inaugural Ameristar National Charity Golf Classic, at one of their premier properties, Ameristar Casino Kansas City. The event raised an incredible $777,000.

“On behalf of all of the tournament sponsors, I am very pleased to make this donation to The Buoniconti Fund and the cutting-edge research it supports at The Miami Project,” said Craig H. Neilsen. “Their work is showing very promising results in finding a cure for paralysis and in improving the quality of life for those living with a spinal cord injury.”

“Over the years, we have been fortunate to have many friends stand up for those who can’t. We appreciate the tremendous support and generosity of Ameristar Casinos and Craig H. Neilsen. The success of this tournament is a true testament to the character and achievement of this man. Craig’s life should be a source of inspiration to all people – especially those of us paralyzed,” said Marc Buoniconti.

Eighth Annual Ricky Palermo Spinal Injury Research Golf and Dinner Extravaganza

On August 6th, Ricky, his family and the entire Batavia, NY community rallied together for the Eighth Annual Spinal Injury Research Golf and Dinner Extravaganza. 216 golfers started the day by playing at the Terry Hills Golf Course and then enjoyed dinner and an auction at the Genesee Community College. Every year this tournament becomes larger and more successful. “I can’t begin to thank my family and the Batavia community enough for the support they give me every year,” said Ricky Palermo. In 1981, Ricky suffered a spinal cord injury and became paralyzed in a car crash.

Tenth Annual Bill Bursis Golf Tournament

On September 14th, Bill Bursis once again held his most successful tournament to date. This year’s event was a milestone as the golf tournament has raised more than $400,000 in total for The Miami Project. More than one hundred golfers came together to celebrate their friend at the Woodloch Springs Country Club in Pennsylvania. A dinner and silent auction was held after the golf tournament. Miami Project Scientific Director W. Dalton Dietrich, Ph.D. and his wife, Dr. Helen Bramlett attended the event and spoke about The Miami Project’s research programs.

Spinal Cord and Brain Tumor Golf Benefit

Injured in 1995, Tim Pelleccone was determined to raise money and increase the public’s understanding of paralysis-related issues. On August 7th, Tim and 134 golfers descended upon the North Kingstown Municipal Golf Course in North Kingstown, RI to raise money for The Miami Project and the Brain Tumor Association.

Joe Bamberg Open

The weather cooperated and the rain held off as 120 golfers congregated at the 1st and 10th tees at the Hillview Country Club to listen to Kyle Addison Knipple sing the National Anthem to kick-off the Eleventh Annual JBO golf tournament on July 18th. The tournament is named after Joe Bamberg who was injured in 1995. Everyone enjoyed the post-golf dinner celebration hosted by organizers John Bonish, Bill Horan, Desi Catena, Scott Garrant and the Bambergers.
Celebrities and friends of The Buoniconti Fund flew from all over the world to attend the Fourth Annual Buoniconti Fund Celebrity Golf Invitational presented by the Tudor Group at Jack Nicklaus’ prestigious course, The Bear’s Club. Nicklaus and his family have opened their club and their hearts to the organization yet again and helped us get more than $575,000 closer to finding a cure.

Golfing legend, Jack Nicklaus and our celebrity pals including NFL Hall of Famer Barry Sanders and Joe Namath, NFL legend Lawrence Taylor, NFL’s winningest coach Don Shula, Olympic Gold Medalist swimmer Gary Hall, Jr., baseball Hall of Famer...
Gen. Norman Schwarzkopf, Marc and Nick

Mike Schmidt, NBA Hall of Famer John Havlicek, baseball great Jeff Conine and Hall of Fame linebacker and Miami Project co-founder Nick Buoniconti teed up for a spectacular day of golf on Nicklaus’ perfect golf course including the chance to win a Hummer 3. Golfers and partygoers feasted on a magnificent dinner while bidding away at the unique auction items. This two-day event has raised more than $2 million over the past four years.
They want to walk again.
Will you help them?

The Project

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