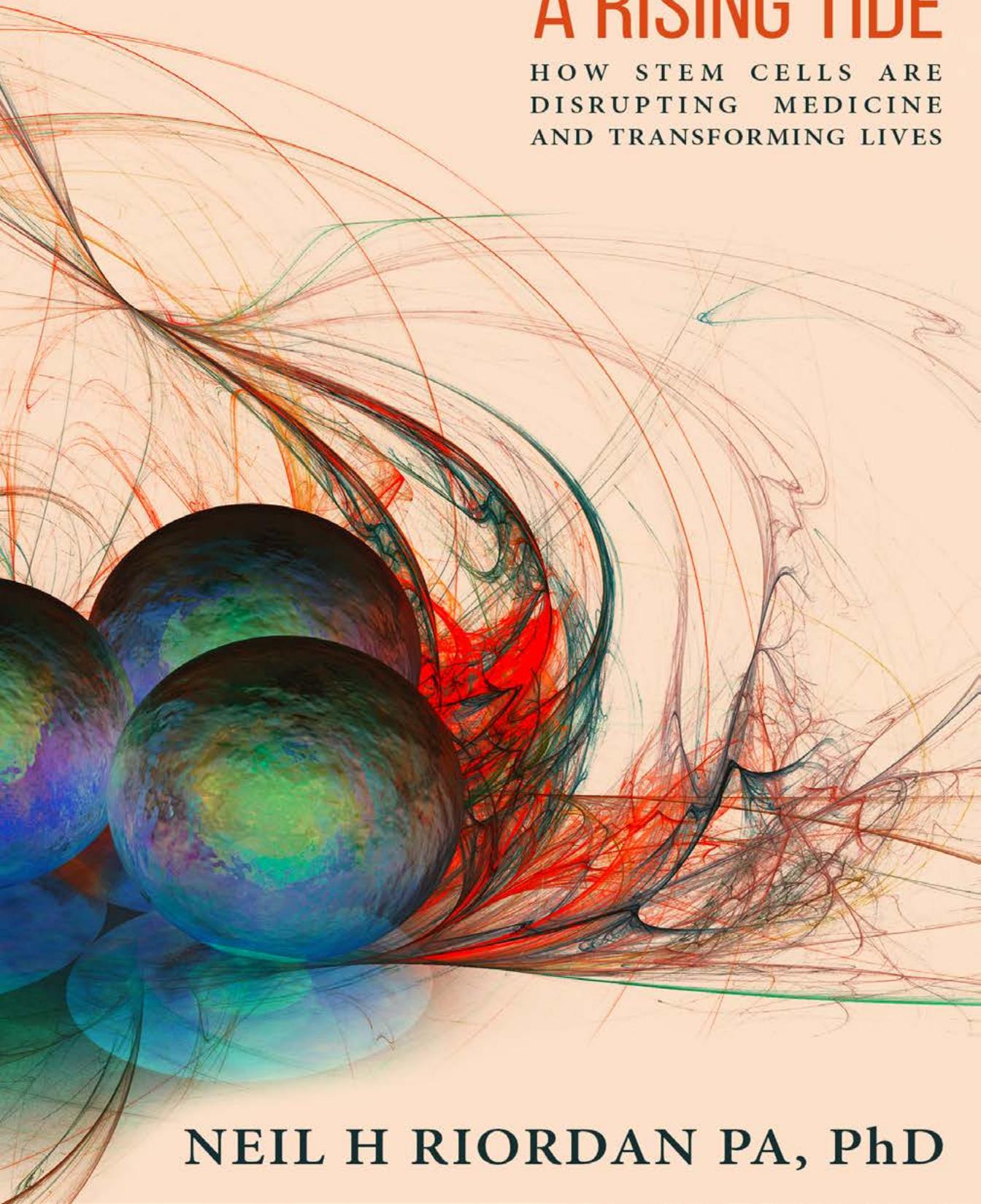


STEM CELL THERAPY

A RISING TIDE

HOW STEM CELLS ARE
DISRUPTING MEDICINE
AND TRANSFORMING LIVES



NEIL H RIORDAN PA, PhD

"Neil takes readers on a riveting journey through the past, present and future of stem cell therapy. His well-researched, educational and entertaining book could change your life. I highly recommend it."

Tony Robbins, NY Times #1 Bestselling Author

"100 years old will soon become the new 60. Stem cells are a key therapeutic to enable this future. Dr. Riordan's book is your guide to why this is true and how you will benefit. A must read for anyone who cares about extending their healthy lifespan."

Peter H. Diamandis, MD; Founder, XPRIZE & Singularity University; Co-Founder, Human Longevity, Inc.; Author of NY Times Best Sellers *Abundance* and *Bold*

Stem cells are the repair cells of your body. When there aren't enough of them, or they aren't working properly, chronic diseases can manifest and persist.

From industry leaders, sport stars, and Hollywood icons to thousands of everyday, ordinary people, stem cell therapy has helped when standard medicine failed. Many of them had lost hope. These are their stories.

Neil H Riordan, author of *MSC: Clinical Evidence Leading Medicine's Next Frontier*, the definitive textbook on clinical stem cell therapy, brings you an easy-to-read book about how and why stem cells work, and why they're the wave of the future.

"I'm the luckiest guy in the world. Stem cells have given me my life back."

Sam Harrell – Football coach and Multiple Sclerosis patient

"I never want to go back to autism before stem cells."

Marty Kelly – Parent of a child with autism



NEIL H RIORDAN, PA, PhD

Neil H Riordan is an accomplished scientist and developer of regenerative medicine therapeutics, with more than 70 peer reviewed publications and more than 40 patents and patent applications to his credit. He is the author of *MSC: Clinical Evidence Leading Medicine's Next Frontier*, a groundbreaking compilation of stem cell studies for more than 30 medical conditions, with over 800 references to peer-reviewed articles. Dr. Riordan founded Medistem Panama, a leading stem cell laboratory and research facility that is ISO 9001 certified and fully licensed by the Panamanian Ministry of Health. He also founded the Stem Cell Institute in Panama, where his mesenchymal stem cell technologies continue to be implemented in patients, now numbering in the thousands, with autoimmune and degenerative diseases and injuries.

Stem Cell Therapy A Rising Tide

**How Stem Cells are
Disrupting Medicine and
Transforming Lives**

Neil H. Riordan

Stem Cell Therapy: A Rising Tide
How Stem Cells are Disrupting Medicine and Transforming Lives

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This book is not intended as a substitute for the medical advice of physicians. The information provided in this book is designed solely to provide helpful information on the subjects discussed. The reader should regularly consult a physician in matters relating to their health and particularly with respect to any symptoms that may require diagnosis or medical attention. While all the stories in this book are true, some names and identifying details have been changed to protect the privacy of the people involved.

Layout design by www.iPublicidades.com

Illustrations by
Blake Swanson – Innercyte: Medical Art Studios
Steve Lewis – Blausen Medical
Stem Cell Institute & Riordan-McKenna Institute

Covert design by n23art

Printed in the United States of America.
First Printing: 2017
ISBN: 978-0-9990453-0-5

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Foreword

As I read this book, I became very emotional. I had to go back about 28 years ago when my wife and I sat in a doctor's office and listened to a neurologist list in grim detail how our beautiful three-year-old son Ryan would spend his next 20 years. The doctor told us there was nothing that they could do at that time. He suggested that we do everything we could to keep Ryan active in order to maintain the strength he had as long as possible. And hopefully in the next 20 years they might find a cure for muscular dystrophy. The prognosis changed our lives forever. It was a very painful time for all of us.

As I continued to read about all of the patients who have been treated by Dr. Riordan, I realized that we all had one thing in common: traditional medicine had given up on us. There was nothing that could be done. Our own government, founded on the premise of life, liberty, and the pursuit of happiness, had evolved into overreaching bureaucracy that would attempt to prevent us from seeking lifesaving alternative treatments.

But once again, we all had something else in common. We found a man who was willing to do everything in his power to offer us options and give us hope for the future of our loved ones. Dr. Riordan has truly dedicated himself to his profession as a medical pioneer. He has sacrificed everything he has to give those who have been told there are no options a fighting chance and real hope for the future.

Dr. Riordan has never wavered in the face of scrutiny. It takes true courage to stand up to the often judgmental “traditional” medical community—those who act offended when you suggest that there might be a different way.

Fortunately for all of us, Dr. Riordan had the foresight to look beyond the walls of traditional medicine and fight the fight for us. I encourage you to read this book, and not just the chapters related to your condition. As a whole, the book lays out Dr. Riordan’s courageous and successful journey through his stories and the stories of his patients.

Thank you, Dr. Riordan, for all that you have done for us and our families. You truly are a hero!

George Benton, Ryan’s father

Introduction

BY ARNOLD CAPLAN, PHD

Neil Riordan, PhD, PA is a pioneer of the highest order, in some ways like John Glenn or Neil Armstrong. Neil has ventured where the routes were uncharted and the dangers huge. His rocket of cell therapy was launched on a rickety platform filled with hopes and dreams, and powered by an engine of money. This pioneer has hacked his way through the jungle of naysayers and has produced miracles of enormous proportions. He has taken our scientific dreams and translated them into a high-caliber medical facility that does good by offering exposure to cell therapy treatments that we working scientists only dream about.

Although there are those in my professional realm who would say that Neil is a medical “cowboy” who “experiments” with human subjects, I would say that he is providing access to therapies that are no more experimental than one sees every single day in the surgical suites of major medical centers. In such situations, the surgeon is “forced” to improvise because of the complexity of the wound field. Such improvisation sometimes involves using materials that are not approved but that the surgeon “feels” will work well in the situation he faces. For example, human decellularized skin from dead people was approved for topical applications for ulcerated wounds in diabetic patients. But these “membranes” are fabulous for closing abdominal surgical wounds in hernia repair operations and have changed the way such closures are done. This surgical improvisation, originally performed by a “cowboy” surgeon, is now the standard of care. We move forward in medicine by the skill and insightful work of pioneers—some with IRB approval and some not. Riordan’s procedures with MSCs currently have IRB approvals.

In a sense of transparency, let me say that I have accepted honoraria from Neil Riordan and gifts of hotel rooms, meals, and, indeed, infusions of MSCs. These all have monetary value, but none influences my opinion. The monetary success of Neil's enterprises evoke jealousy in some entrepreneurs, but Neil's continual reinvestment of money into his next medically successful enterprise displays his true motives—the advancement of a medically necessary science despite great obstacles. The key to his success is in the enormously high quality of his facilities; the people, doctors, nurses, receptionist, PR team, etc. are *all* highly principled and care about the patients they serve. These people care about what they do because Neil recruits them for their skills and attitude. He does not discuss this in this book, but they are present on every page. He talks about Dr. Paz, but he does not tell you of his long medical experience and his reputation in the United States and in Panama for caring and experienced medical judgements. In all of Neil's clinics, quality control labs, hotels for patients, and restaurants where they eat, the staff behind the scenes are dedicated to providing the highest quality medical care possible. Some clinics and hospitals in the United States could take lessons from the Riordan gang. That said, the cell-based therapies Neil's clinics provide have not all been approved and tested by double-blind, placebo control and rigorously monitored clinical trials, although such trials are currently underway. But, like innovative surgeons, these open-label uses have proven effective, as hopefully we will see in published peer-reviewed reports of his studies.

Each chapter of this book recounts the personal stories of how Neil's unwavering confidence that cell-based therapies with MSC preparations from fat, marrow, or umbilical cords can make a medical difference. Neil made medical tourism work, and what he has done is highly laudable, not only because of the patients he has helped, but because of the laws that have been written to support cell-based therapies in Panama. This book is not what I pleaded with Neil to write, however. I have, for many years, begged him to give us outcome reports of his many patients: what they have as clinical problems, what they walk in with, and the longitudinal outcomes after the cell infusions. Hopefully these will be forthcoming, but they are not in this book. What is here in these pages is, none-the-less, amazing.

I first learned about Neil's clinic in Costa Rica and thought his procedures and therapies were brilliant. And these were crude compared to those currently underway in Panama. The Panama GMP-production facilities, his offices and treatment rooms, and the products including MSCs from umbilical tissue are of the highest quality. These are the vehicles and the platform that allow him to write this treatise of the therapies they provide. It is a shame that we have to fly to Panama to have access to these therapies instead of having them available in the United States. How long will it take for such therapies to be available to the patients covered by Medicaid or Medicare instead of those from Beverly Hills or Long Island who can afford to travel to Panama?

Almost daily I receive emails from people who want access to "stem cell" treatments. I tell them that I am just a PhD researcher and cannot suggest an avenue of treatment for medical issues. If you have this book in hand, read the chapters. They are honest, open, and spellbinding. While Neil is not a medical doctor, his clinical experience as a physician assistant along with his research background have prepared him for the serious medical issues for which Neil has organized cell therapy treatments, often with quite significant outcomes. Neil is certainly a student of the medical arts and an expert using innovative treatments. I have talked to patients of Neil's clinics and their family members about their treatments; the stories told in this book are just the tip of the iceberg. This is an interesting book and an interesting and gutsy journey of Neil Riordan. His physician father would be proud to recognize Neil's passion and medical achievements.

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January 15, 2017

Chapter Six

SPINAL CORD INJURY— THE ULTIMATE REPAIR

Juan Carlos Murillo was a skillful pilot so deft in navigating a small plane that he was hired by a *National Geographic* photographer who wanted to take pictures of the mountainous Pacayas valley in Costa Rica back in May of 2008. The day was cloudy and the plane was buffeted by wind, but Juan Carlos and his passenger had been soaring smoothly over the valley floor and close to the highest peaks. Suddenly, two hours into the flight, Juan Carlos knew that something was wrong. The plane had endured turbulence off and on throughout, but it started to lose altitude. As he struggled to right the aircraft, he warned the photographer to get ready to make an emergency landing.

Juan Carlos wrestled with the aircraft, doing his best to make the impact as minimal as possible—what aviators call a controlled fall. The belly of the plane skipped twice over the valley floor before it came to a stop near a populated area. The plane was quickly surrounded by people. As Juan Carlos waited for the rescue vehicles to arrive, he thought he and his passenger were going to be just fine because their legs and feet, usually the first casualties of a crash, were intact. But when the helicopter arrived to transport them to the hospital and the emergency medical team maneuvered him out of

the cockpit, Juan Carlos realized that something was very wrong with his back.

At the hospital, the MRI revealed that the spinal discs in his low back—at vertebrae L1 and L2—were completely crushed. There was nothing left of them. The doctors rushed him into surgery to stabilize his spine, but they had to stop the operation midway because of bleeding. The next day he had two more surgeries, one to stop the bleeding and another to stabilize his back. A week and a half later, his doctor transferred him to a long-term care hospital where he stayed another five weeks without making much progress in getting sensation below his waist. As he checked out of the hospital at the end of that discouraging stay, the looks on the faces of the staff told him what they believed his prognosis was. His doctor said that Juan Carlos would never walk again.

His doctor said that Juan Carlos would never walk again.

Immediately after the bleak prognosis at the second hospital, he checked in to another rehabilitation hospital that seemed as though it might offer some hope. There they kept him immobilized in a harness and strapped into a brace. Instead of soaring a mile above Earth in a plane as he was used to, the only thing he could see for the six weeks of his stay was the ceiling over his hospital bed. When he checked out of this hospital, the doctors again said they were sorry, Juan Carlos would never be able to walk again.

Undaunted, Juan Carlos signed up for a demanding course of physical therapy at the clinic run by a talented physical therapist, Eugenia Paris, who specializes in spinal cord injuries. What Juan Carlos didn't know when he committed to working with her is that Eugenia is a proponent of stem cell therapy. I have been sending my spinal cord injury patients to her physical therapy center since our clinic first started treating spinal cord injury patients with stem cells, but Eugenia had advocated for the treatment before that.

Eugenia had had a spinal cord patient who went to Germany for stem cell treatment and noticed some improvement in his condition. As she says, for a spinal cord injury, a little bit of improvement is a huge event for most patients. Patients who cannot move at all and then find they can

manipulate a joystick, or stand in the kitchen with the help of crutches while their spouse makes dinner, are thrilled by these advances. Almost from the time Juan Carlos entered her clinic, Eugenia insisted that he try stem cell therapy for his injury. In fact, the first time Eugenia laid eyes on Juan Carlos she contradicted what every other medical professional predicted. “You are going to walk again,” she said. “Don’t worry.”

At first Juan Carlos resisted. His family had sent him to several psychiatrists to help him handle the sad reality that he wouldn’t be able to walk again. When he told his father, a respected obstetrician in Costa Rica, about the stem cell option, his father was very doubtful. He’d never heard of the treatments we were doing and suspected that they might harm his son. After all, Juan Carlos’ father had paid for his son to travel to Miami and consult with some of the most respected spinal cord injury specialists in the world. Those doctors examined Juan Carlos’ MRI and repeated the hopeless predictions of his Costa Rican physicians.

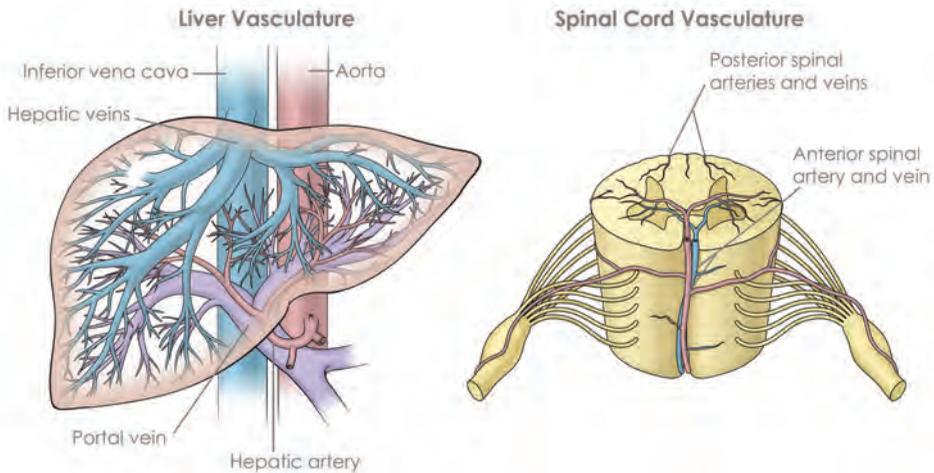
Eugenia was undaunted. She argued with Juan Carlos for two months, trying to persuade him that our treatment at the very least would do him no harm and, because he was so young and had been so active, had a good chance of making significant improvements. She knew he was a good candidate for stem cell treatment.

I had decided when we set up our clinic in Costa Rica that we would treat one local patient free for every twenty paying patients we took. I offered Juan Carlos one of the pro bono slots, and he persuaded his family this was the next best step, in fact the only step that offered some hope of recovery.

When a traumatic blow injures the spine, as happened to Juan Carlos, the impact pulls the nerve fibers apart and the pressure on the cord damages the blood vessels and the nerves. The pressure on the spinal canal rises and, as Juan Carlos experienced, there is a tremendous loss of blood. With the spinal cord depleted of blood and flooded with chemicals from the disrupted membranes, the body’s immune response quickly forms scar tissue to protect the area. This is why spinal cord injury experts like to try to repair the area as quickly as possible—before the wounded spinal cord becomes scarred in.

Until recently, there was really nothing that could be done about spinal cord injury. A person with this injury would be disabled for the rest of his or her life. It makes sense, from an evolutionary standpoint, that the body puts great energy and resources into creating this wonderful cage, full of strong bones, around the spinal cord (the spinal column). It would have been a waste of resources to put a high concentration of MSCs in the spinal cord with all the protection already constructed. (This is similar to what has happened with vitamin C. At one point in our evolutionary history, humans lost the ability to produce their own vitamin C because we consumed enough of it from food. Mother Nature does not waste.) Capillary density of white matter is one fifth that of gray matter.¹ Capillary density of gray matter in the spinal cord is approximately three times less than that of liver tissue and ten times less than that of heart tissue.² Therefore we can assume that, since all MSCs live on capillaries, during a spinal cord injury many fewer MSCs are released, which is why the spine does not fully regenerate. This is in sharp contrast to the liver, which can nearly completely regenerate.^{3,4,5}

Comparison of Vascularity



Comparison of the vasculature in the liver (very highly vascularized) and in the spine (sparsely vascularized).

Mesenchymal Stem Cells for Spinal Cord Injury

The spinal cord is a long, delicate bundle of nervous tissue encased and protected by the vertebrae and segmented into regions according to the position of the nerves: C1 to C8 (cervical), T1 to T12 (thoracic), L1 to L5 (lumbar), and S1 to S5 (sacral). A spinal cord injury (SCI) occurs when the tissue is torn, bruised, or crushed in an accident (traumatic) or by the progression of a disease or disorder (non-traumatic). The most common cause of SCI is physical trauma.

Magnetic resonance imaging (MRI) is used in SCI to pinpoint the level and extent of the lesion. The level of the injury depends on the vertebra (e.g., C3, T10). A complete SCI is one in which no function remains below the level of the injury whereas for an incomplete SCI some limited function does remain. Scales exist to measure motor and sensory limitations (ASIA scale, MEP/SSEP) and quality of life (ADL, SF-36, ODI) in SCI patients.

We'd had good results using umbilical cord cells to treat spinal injury, but Juan Carlos' dad still wouldn't agree to the procedure. He didn't want to subject his son to a treatment he considered to be unproven, partially because he'd never heard about it in medical school. Eventually Juan Carlos convinced his dad that it was his life and, in the shape he was in, he had nothing to lose. His dad respected his son's wishes and even provided umbilical cords from his own patients for the treatment. Once we received the cords, we harvested and expanded the stem cells to repair the damaged spinal cord, just as we continue to do in our clinic in Panama today. They are administered both intravenously and intrathecally (via the spinal fluid). We added the use of concentrated bone marrow to our protocol after Juan Carlos was treated. So, in addition to the umbilical cord cells, the bone marrow cells are given both in the vein and in the spinal fluid. Spinal cord injury is the only condition we treat using bone marrow. There are several studies now that show cells concentrated from the patient's own bone marrow as sole therapy can improve the functionality of spinal cord injury patients. The main reason we use the bone marrow is because in addition to containing MSCs, it is rich in CD34+ cells and endothelial precursor cells (EPCs). Both cell types potently stimulate new blood vessel growth. Most spinal cord

Changes in motor and sensory functions are usually seen after a spinal cord injury, caused by a loss of neurons and axons as well as inflammation and damage to the protective nerve covering known as the myelin sheath (demyelination).⁶ Since communication below the level of the injury is affected, significant loss of quality of life and many other complications may arise, such as hypersensitive sensations, pain with no sensation, extensive pain along the damaged fibers, involuntary spasms or reflex actions, respiratory infections, bone density loss, muscle tone damage, pressure ulcers, and problems with sexual function.⁷

Researchers at Cambridge University in the United Kingdom, at Purdue University in Indiana, and at Washington University in St. Louis have had success treating spinal cord injuries in dogs and rats with stem cells. They tagged the cells with a radioactive marker so they could follow where the cells rested in the body as they migrated through the bloodstream. They tracked them to the site of the injury where some persisted and delivered growth factors that helped in the repair of the damaged spinal cord. Other researchers investigating how to regrow the spine looked into the immune system

injuries are traumatic and lead to a loss of blood flow to the spinal cord area, which has very few blood vessels in the first place, compared to other tissues and organs. Creation of new blood vessels with these cells is very important to stimulate healing.

Juan Carlos had his first treatment in October of 2008 and found great relief from his phantom neuropathic pain. It went from a ten to a three on a scale of one to ten and he was able to stop taking narcotic pain relievers. It wasn't until the second treatment at the end of February 2009 that he started to feel the stem cells working on restoring feeling. The next week, in the beginning of March, for the first time in almost a year Juan Carlos started to feel the muscles of his legs contracting, and he could move his toes. In physical therapy, Eugenia was working with him to move more, stimulating his legs electronically with probes—suddenly he started to feel his knee.

Eugenia began working with Juan Carlos to help him build up his strength. He'd lost nearly fifty pounds since the crash. Confined to bed and unable to control his bladder, he had been subsisting on liquids. He was embarrassed that he had to wear a diaper. His muscles were starting to atrophy. Eugenia and her staff put him on the parallel bars to help him stand

response, which is complex. Spinal cord injuries trigger an autoimmune reaction to try to protect the other nerve cells from damage. It seemed clear that to help repair a human spine, MSCs would have to serve multiple functions: deliver growth factors to the spine that would help the cells regenerate, decrease scarring and inflammation, and shut down or modulate an inappropriate immune response.

Repair of the spinal cord is critical to recover mobility and function. The regenerative, anti-inflammatory, and angiogenic activities of mesenchymal stem cells (MSCs) have stimulated numerous preclinical studies in the area of SCI. The rationale for the treatment of our first SCI patient in 2007 came from a case report in Korea, in which a patient treated with umbilical cord blood stem cells was found to be able to move her hips and feel her hip skin 15 days after treatment.⁸ After this, she began to elevate both lower legs about one centimeter, and muscle activity around her hips gradually improved. Tests taken 41 days after treatment showed regeneration of the spinal cord at the injured site and below it. This was supported by several studies of injured rats treated with cells from human

up while he practiced walking. They gradually coached him to put more and more of his body weight on his feet to help him regain control of his leg muscles and build up his strength. In a matter of just a few months, he went from walking with the help of a therapist and the parallel bars to a walker, then crutches, and finally to a cane. In May 2010, two years after the crash, Juan Carlos was able to walk without any assistance. That summer he was able to fly again, and requalified as a pilot. His recovery was amazing.

During the period when Juan Carlos was being treated, we had opened a new laboratory in Panama City, Panama, in the City of Knowledge, a converted military area located in the former Panama Canal Zone. The City of Knowledge is a government-sponsored cluster of academic organizations, research and technology companies, and non-governmental organizations. At the same time we opened the Stem Cell Institute, a research-based medical facility at the campus of Punta Pacifica Hospital.

In November 2010 when I was visiting the Stem Cell Institute, I was having a drink with some staff and a few friends in a bar near the clinic. Who walked in but Juan Carlos, holding hands with his lovely fiancée. With three treatments using carefully targeted injections of refined umbilical cord

umbilical cord, showing improvements in function and some restoration of the spinal cord tissue.^{9,10,11,12} In these cases, the cells survived without immune suppression, migrated to the site of injury, and enhanced recovery significantly. Treatment with bone marrow MSCs was also demonstrated to be safe and feasible for treatment of SCI.^{13,14}

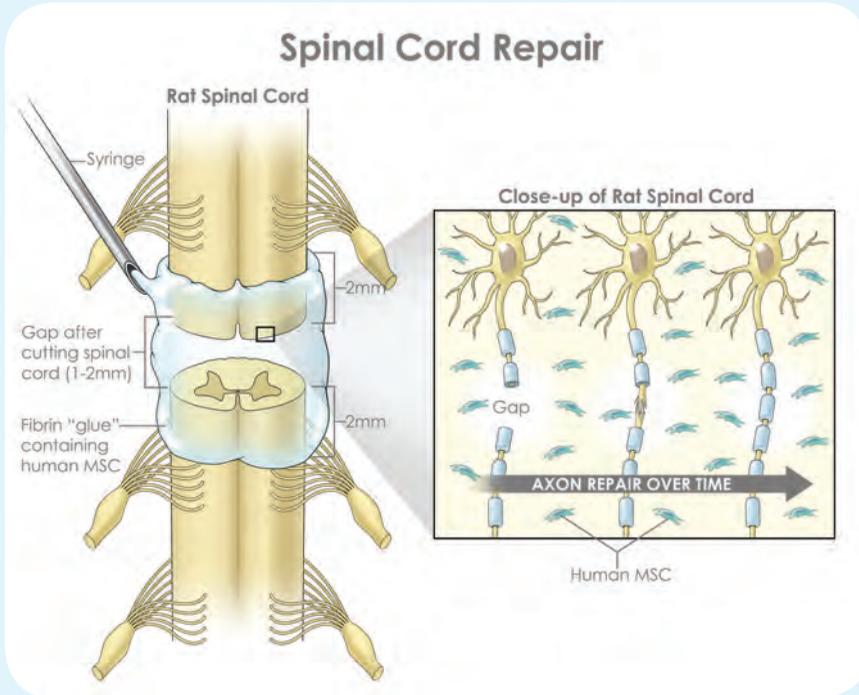
Perhaps the most compelling early animal trial for the treatment of SCI, published in 2008, contains both the rationale for their use in repairing the spinal cord and an elegantly designed study that demonstrated that the beneficial effects were from the secretions of the cells and not from the cell becoming spinal tissue.¹⁵ The researchers completely severed the spinal cords of rats and then placed human umbilical cord mesenchymal stem cells over the fibrin glue that covered each severed end. The MSCs homed to the site of injury, secreting proteins that encouraged regeneration, calmed inflammation, and modulated the immune response in such a way that the spinal cord was able to regrow. The MSCs simply stimulate the natural repair process. As mentioned several times in this book, the beneficial effects of MSCs are due to their secretions and not from their “becoming” another

stem cells, Juan Carlos had regained 90 percent of what he’d lost because of the accident.

“I know this seems like a miracle, and it would be miraculous to the millions of people who suffer right now from paralyzing spinal cord injuries to think that with a combination of adult stem cells and extensive physical therapy they, too, could regain use of their spines, control of their bowels, and full sexual function. Yet it is not a miracle. It’s basic, simple science that even some of the most prestigious specialists in spinal cord injuries have yet to attempt.”

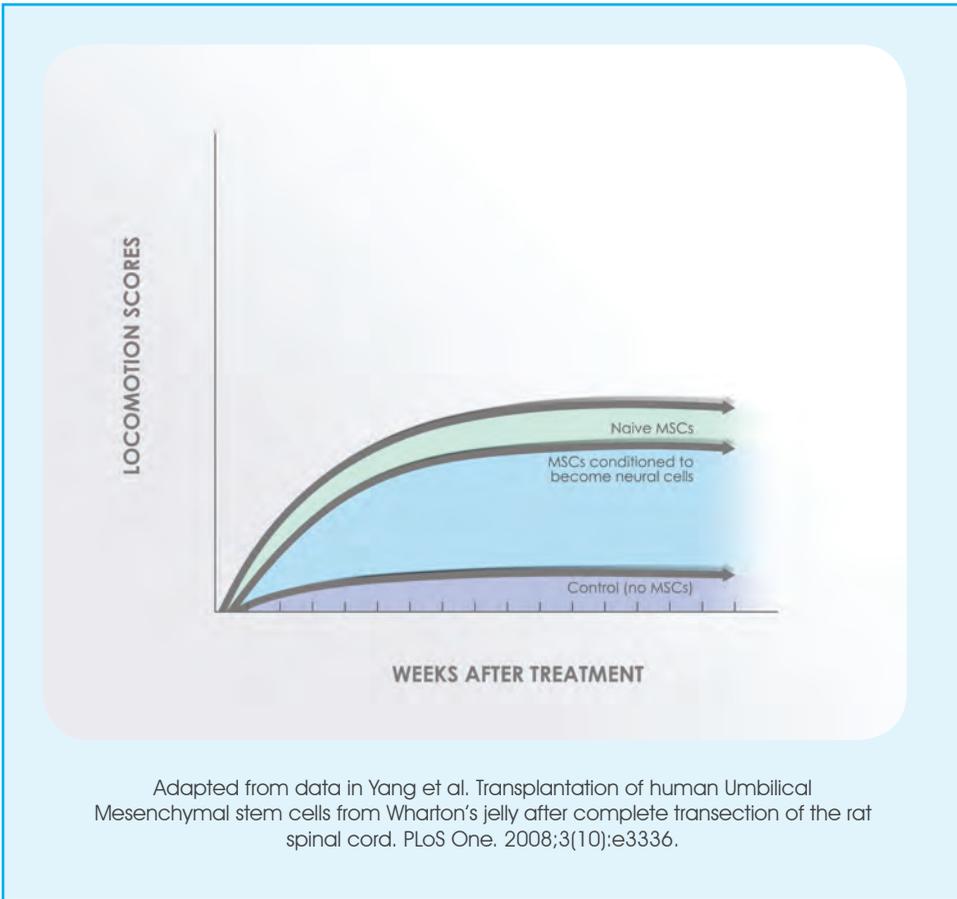
I will never forget giving grand rounds at a prestigious U.S. university that is well known for its pioneering work on spinal cord injury. The researchers had never heard of umbilical cord cells or bone marrow from the patient

kind of tissue. An important contribution of this study is that the umbilical cord MSCs that had not been altered (had not been induced to become spinal tissue cells) worked better for repair than those that had. More importantly, because the cells were human, they could be identified in the tissue. After the spinal cords regrew, the human cells were found only between the regrown fibers and were not part of the spinal cord itself. It's not the cells themselves that are required for healing, you see, but rather, what they secrete.



Adapted from data in Yang et al. Transplantation of human Umbilical Mesenchymal stem cells from Wharton's jelly after complete transection of the rat spinal cord. PLoS One. 2008;3(10):e3336.

as being useful for spinal cord injury. I presented six articles that were in the literature showing benefit in humans by treatment (i.e., restoration of neurologic function) with umbilical cord cells and bone marrow cells. They were unaware of the studies, having been focused only on their own cell type, for which they had a laundry list of patents. These included not just the cell type but the methods for isolating and growing them in culture. Oftentimes this is the biggest problem in clinical research for the treatment



of disease—conflict of interest. Rather than focusing on what works, industry and academia focus on what they own. I saw this with my own company, Medistem, Inc, a U.S.-based publically traded company. We had patents and patents pending out the wazoo on the menstrual mesenchymal cell (also known as the endometrial regenerative cell, or ERC). At the time, in 2007, we were doing some research on heart failure. We had a cohort of subjects that were treated with umbilical cord cells and the majority of them improve dramatically. The board of directors wanted to try using the menstrual cells, and we did. That cohort did not do nearly as well. We had to bring them back and treat them again with the umbilical cord cells. It was at that time that I knew we needed to part ways with the U.S.-based company, which was interested only in promoting what it owned. At the Stem Cell Institute we

Years after these initial studies, the effects of MSCs on SCI are still being demonstrated.^{16,17,18} A recent review presents 21 animal studies with demonstrated therapeutic effects of MSCs in preclinical models, with significant improvements in mobility, sensory tests, and motor function.¹⁹ Treatment with MSCs for SCI has entered clinical trials—a survey of ClinicalTrials.gov returns several ongoing and recruiting MSC trials.^{20,21,22,23,24} A recently completed trial reported motor improvements in eight out of fourteen SCI patients safely treated with umbilical cord MSCs, with significant differences in ASIA scores as motor and sensory functions before and after treatment.²⁵ Other clinical trials with bone marrow MSCs also showed improvements for 50 to 75 percent of patients.^{26,27} In our clinical experience, treating SCI with umbilical cord MSCs brought significant changes in pain scores and mobility, as well as recovery of bowel and sexual function, as we saw with Juan Carlos.²⁸

We are conducting a phase I/II clinical trial in our Panama clinic to assess the safety and efficacy of intravenous and intrathecal allogeneic umbilical cord MSCs and autologous bone marrow MSCs for patients with spinal cord injury. Additionally, we are in the process of starting an umbilical cord MSC clinical trial in association with the University of Miami and Thomas Jefferson University, funded by the Marcus Foundation.²⁸

were, as we always have been and are to this day, only interested doing what was best for the patients.

When I saw Juan Carlos in Panama he was visiting for a fourth treatment. He still had some stiffness in his right ankle and some spots on his right leg that were numb. He wanted to see if another treatment could eliminate the last traces of his injury.

Juan Carlos had made a remarkable improvement. He was so proud of what we had all worked so hard to achieve that he flew back to see the world-renowned back specialist in Miami who had glumly told him that he would never be able to walk. When he walked into the doctor's office for the appointment, the doctor didn't believe it was him. And his father, the conventionally trained obstetrician who was so skeptical of stem cell treatment at first, now educates other doctors and his own patients about the therapy.



Juan José Vallarino was 30 years old in 2009 when he tripped and fell down a river bank, landing on his neck. “It was like something snapped,” Juan José said. He called his mom on the way to the hospital to say goodbye, unsure if he would survive. At the hospital, doctors determined that he had a complete C5, C6 spinal cord injury. He was completely paralyzed from the neck down. “I didn’t know when I was being touched. It’s a crazy feeling all over the body.” After spinal surgery eleven days later, and hospital discharge seven days after that, he was wheelchair bound with difficulty breathing and without bladder or bowel control. He could move only his eyes and mouth.

After eight months of rigorous physical therapy, and with the help of two people lifting him into position, he was able to stand on his own while holding himself up. He had gained movement in his arms and could wiggle one of his toes. But he longed to do more. “The first two years were pretty bad,” he said.

By the time he had heard about stem cell treatment four years later, he was still unable to wheel himself in his wheelchair, transfer himself from the chair to the toilet, or dress himself without great difficulty. He had no urinary control and was chronically constipated. He had very little independence. He would wake up in the morning screaming with neuropathic pain. “It was like 15 on a scale of one to ten,” he said of his pain. “I feel as though I didn’t sleep for four years. The pain was everywhere.”

After his first stem cell treatment at our clinic in Panama, his pain subsided. He gained the ability to transfer himself to the toilet and into the car. He could pull himself up when needed and could put on his shirt. He started doing exercises on his own. “Putting the training together with the stem cells was great,” he said. Perhaps best of all, he regained urinary and bowel control as well as erectile function.

“When you can’t move, it’s like you’re a plant, just waiting to be fed, given a shower, clothed, and put back in your chair where you stay. Now people can have a chance to get better.”

After his second treatment two years later, he has regained independence—he now lives on his own. He can completely dress himself and uses a gait training walker to move about the house and go outside. “When I stand up I can feel my glutes and my lower back muscles contracting. I can hold a fist now when before I couldn’t.” He continues to train twice daily, five days a week. “Every case is different, but what the stem cells have done to me is amazing. You have to put in a lot of effort.” He’s right. Our spinal cord injury patients undergo an intensive physical training regimen that we recommend they follow long term when they return home.



Juan José is enthusiastic about his progress with stem cells. “When you can’t move, it’s like you’re a plant, just waiting to be fed, given a shower, clothed, and put back in your chair where you stay. Now people can have a chance to get better.”



The first spinal cord injury patient we ever treated was in early 2007. He was a 23-year-old from Florida who had been in a motorcycle accident three months prior, which had paralyzed him from his T4 vertebra, at the level of his chest, down. He showed up with his doctor one day at our clinic asking to be treated, strapped to his wheelchair because he couldn’t engage his abdominals or obliques to hold himself up.

He was treated for eleven days, and before he left he was able to bend from side to side and lean forward all on his own. He had gained feeling and movement down to his hips and was able to transfer himself out of bed and into his wheelchair for the first time. He came back a year later for another treatment and gained more function, including erectile function.

As of this writing, we've treated 116 patients for spinal cord injuries, including Iraq War veterans. Seventy percent of them have experienced restoration of some function. What we tell them at the first appointment is that they shouldn't hang all their hopes on walking again. The least we can work toward is for them to regain control of their bladder function. This is a great step forward from being hooked up to a catheter all day. We tell them to go slowly with their expectations. Just like relearning to walk, they have to take it one step at a time. But there is incredible hope here, particularly if we can get to the patients before significant scar tissue has had a chance to form, and if we can get them working with a physical therapist right away. We always tell patients that our spinal cord injury treatment protocol is 50 percent stem cell therapy and 50 percent physical therapy. You don't get the kind of results Juan Carlos did without a physical therapist who is always urging you to do more, to work harder, and to never give up hope.

Unfortunately, many people come to us after suffering for years with a spinal cord injury and we have to turn many of them away because too much time has passed since the original injury. But in patients with more recent injuries, our treatment, in combination with physical therapy, determination from the patient, and support from people around them, can lead to dramatic healing. As we continue to refine this protocol and learn from doctors around the world who are working on the same techniques from other angles, we hold out the hope that within the coming years we can end spinal paralysis.

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Chapter Six

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