Working2Walk 2019

Building Advocacy, Empowerment, and Unity towards Finding Cures for Paralysis

October 4 - 5, 2019
Cleveland, Ohio

unite2fight paralysis

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To all of our wonderful sponsors who made this year's Working 2 Walk Symposium possible.

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Contents

How Well Do We Understand the Research Pipeline from Discovery to Treatment?

This is the question at the forefront of our minds. Consequently, it's how we've designed our agenda this year. Why? Because - especially for the SCI Community - it helps us clarify where to place our advocacy efforts and resources.

We think that contemplating this translation wheel (which illustrates the phases of discovery to treatment) is an important exercise, especially for those of us in the SCI Community.

(source: Children's Hospital of Philadelphia Research Institute, Center for Pediatric Clinical Effectiveness)

As you listen to each of the presentations, use this graphic and ask yourself the following questions:

1. Where does the curative science I'm engaged with sit on the translation wheel? And why?
2. Where does this need to go next and how does it get there? What is the tension be tween how much more needs to be known and when the results are good enough to try?
3. Where can we, should we, do we place our efforts to move things along the wheel?

This is our Context Strategy Voice approach in practice. We (both the SCI Community & the Research Community) need to understand where the science is and where it's going so that we can strategically invest our advocacy efforts and effectively increase our voice.

We are foregoing our typical breakout sessions at Working 2 Walk this year by replacing it with a Cure Advocacy Network panel discussion about our state initiatives to pass SCI Research Funding Bills with advocates from Pennsylvania and Ohio. The panel will talk about their experiences talking with legislators, learning about the process for passing legislation and generating attention from within their local communities ... and what's next.

We have also organized a panel discussion as a follow up to the National Institutes of Health's SCI 2020 (A Decade of Disruption) meeting. The panel will consist of stakeholder representatives directly involved in the effort to find curative treatments for Spinal Cord Injury: researcher, clinician, industry, SCI community, and funding. The discussion will be an exploration of three things:

1. How do WE define a 'win' and what obstacles do WE face to achieve that 'win'?
2. What 'disruptions' do WE think are necessary to remove or mitigate the obstacles?
3. What actions can be taken to facilitate those disruptions?

We trust that everyone here wants the same thing: more progress, and faster progress. We believe that we can help to make that happen - **Together**.

Be sure to check out **"Navigating the Working 2 Walk Science Presentations"** section in the middle of this program, as a more detailed companion to the above approach.

And finally - but importantly - **Don't Forget to Thank a Sponsor.** This conference happens because a few organizations write checks to underwrite expenses. Take a moment to speak to them. Let them know how much it means to you that they're here for us.

Onward!
Your friends at Unite 2 Fight Paralysis

SCHEDULE OF EVENTS

THURSDAY, OCTOBER 3, 2019
ARRIVAL DAY

5:00-7:00 pm

Early Registration & Check-In
West Foyer

FRIDAY, OCTOBER 4, 2019

7:30-9:00 am

Registration & Continental Breakfast *Exhibitor Visits*
West & East Foyer

9:00-9:10 am

Opening Remarks & Welcome
Matthew Rodreick | Unite 2 Fight Paralysis
John Chae | MetroHealth

9:10-9:30 am

Epidural Spinal Cord Stimulation for Spinal Cord Injury: E-STAND Update
David Darrow, MD, MPH | University of Minnesota

9:30-9:50 am

The Neurobiological Effects of Stimulating the Nervous System after Spinal Cord Injury
John H. Martin, MD | City University of New York

9:50-10:10 am

Restoration of Function with Implanted Neuroprostheses
P. Hunter Peckham, PhD | Case Western Reserve University

10:10-10:30 am

Facilitated Panel Discussion
David Darrow, MD, MPH | University of Minnesota
John H. Martin, MD | City University of New York
P. Hunter Peckham, PhD | Case Western Reserve University
Matthew Rodreick | Unite 2 Fight Paralysis - Moderator

10:30-11:00 am

Break – *Exhibitor Visits*

11:00-11:10 am

Introduction to Participant Panel
Kim Anderson, PhD | Case Western Reserve University

11:10-12:00 pm

FES/Stim Participant Panel
Panelists (each of whom have a device implanted for the restoration of a variety of functions):
Lynn Wolf, Ian Burkhart, Maria Sutter, Jason Shaw, Jen French, Laszlo Nagy, David Powers
Kim Anderson, PhD | Case Western Reserve University - Moderator

FRIDAY, OCTOBER 4, 2019 (continued)

12:00-12:30 pm	**Question & Answer Session**
12:30-1:30 pm	**Lunch – *Exhibitor Visits***
1:30-1:50 pm	**Regulatory Considerations to Bring Assistive and Therapeutic Devices to the Community: An FDA Staff Perspective** Vivek Pinto, PhD | Food & Drug Administration
1:50-2:10 pm	**Coverage 101+** Susan Miller, MD | Centers for Medicare and Medicaid Services
2:10-2:30 pm	**Facilitated Panel Discussion** Susan Miller, MD | Centers for Medicare and Medicaid Services Vivek Pinto, PhD | Food & Drug Administration Megan Moynahan, MS | Institute for Functional Restoration - Moderator
2:30-2:45 pm	**Facilitated Question & Answer Session**
2:45-3:00 pm	**U2FP Board Member Appeal** Barry Munro, LLB | Canadian Spinal Research Organization
3:00-3:30 pm	**Break – *Exhibitor Visits***
3:30-3:50 pm	**Overcoming Barriers to Functional Regeneration and Plasticity after SCI** Jerry Silver, PhD | Case Western Reserve University
3:50-4:10 pm	**Protein Tyrosine Phosphatase Inhibitors for Spinal Cord Injury Therapy** Marc DePaul, PhD | NervGen Pharma Corp.
4:10-4:30 pm	**Non-Invasive Treatment for Functional Recovery after the Spinal Cord Injury** Jessica Kwok, PhD | University of Leeds
4:30-4:50 pm	**Facilitated Panel Discussion/Q & A** Marc DePaul, PhD | NervGen Pharma Corp. Jerry Silver, PhD | Case Western Reserve University Jessica Kwok, PhD | University of Leeds Alexander Rabchevsky, PhD | University of Kentucky - Moderator
4:50-5:00 pm	**Day 1 Wrap Up**
5:00-7:00 pm	**Networking Reception** East Foyer
	Dinner on your own

SATURDAY, OCTOBER 5, 2019

7:30-9:00 am	**Registration & Continental Breakfast** *Exhibitor Visits* West & East Foyer
9:00-9:10 am	**Opening Remarks & Welcome** Matthew Rodreick | Unite 2 Fight Paralysis
9:10-9:30 am	**Neural Cell Therapy for Spinal Cord Repair** Lyandysha Zholudeva | Drexel University College of Medicine
9:30-9:50 am	**Neural Stem Cell Grafts as a Treatment for Spinal Cord Injury** Alina Garbuzov | University of California San Diego School of Medicine
9:50-10:10 am	**Regionally Specific Spinal Neural Progenitor Cells in a 3-Dimensional Bioprinted Scaffold: Why Specificity Matters** Ann M. Parr, MD, PhD | University of Minnesota
10:10-10:30 am	**Facilitated Panel Discussion with Question & Answer Session** Lyandysha Zholudeva | Drexel University College of Medicine Alina Garbuzov | University of California San Diego School of Medicine Ann M. Parr, MD, PhD | University of Minnesota Alexander Rabchevsky, PhD | University of Kentucky - Moderator
10:30-11:00 am	**Break – *Exhibitor Visits***
11:00-11:20 am	**The Gut Microbiome and Spinal Cord Injury** Phillip Popovich, PhD | Ohio State University
11:20-11:40 am	**Spinal Cord Injury Causes Chronic Liver Pathology and Metabolic Disruption in Rodents** Dana McTigue, PhD | Ohio State University
11:40-11:50 am	**Combined Question & Answer Session**
11:50-12:50 pm	**Lunch – *Exhibitor Visits***
12:50-1:10 pm	**Transcutaneous Spinal Cord Stimulation and Activity-Based Therapy: What Does It Mean for Me?** Rebecca Martin, OTR/L, OTD, CPAM | Kennedy Krieger Institute
1:10-1:25 pm	**Exercise is Medicine: How to Reduce Secondary Complications and Increase Quality of Life Outcomes for Individuals with Spinal Cord Injury (Part 1)** Hal Hargrave | The Perfect Step

SATURDAY, OCTOBER 5, 2019 (continued)

1:25-1:40 pm

Exercise is Medicine: How to Reduce Secondary Complications and Increase Quality of Life Outcomes for Individuals with Spinal Cord Injury (Part 2)
Mike Alpert | President/CEO, The Claremont Club

1:40-2:00 pm

Combined Question & Answer Session

2:00-2:30 pm

Break

2:30-2:35 pm

Introduction to Participant Panel: "SCI2020 - One Funders Perspective"
Kym Eisner, BA, MFA, MNPO | Craig H. Neilsen Foundation

2:35-3:00pm

SCI2020 Panel Discussion
Michael Lane, PhD | Drexel University College of Medicine
Matthew Bellman, PhD | Chief Technology Officer, Myolyn
David Darrow MD, MPH | University of Minnesota
Ernest Wong, PhD | NervGen Pharmaceutical Inc.
Barry Munro, LLB | Canadian Spinal Research Organization
Matthew Rodreick | Unite 2 Fight Paralysis: Moderator

3:00-3:30 pm

Panel Question & Answer Session

3:30-4:00 pm

Cure Advocacy Network (CAN) Panel Discussion
Jake Chalfin | Pennsylvania
Allie Leatherman | Ohio
Peter Nowell |Ohio
Jeni Belt | Ohio

4:00-4:20 pm

Panel Question & Answer Session

4:20-4:30 pm

Conference Wrap Up

End of Conference

NOTES

WE STAY TRUE

To our roots.

MAKE YOURSELF

Comfortable.

SPONSOR EXHIBITORS

Our sponsors help make Working 2 Walk possible - they also provide a tremendous array of resources, services and products for the SCI Community. Sponsors will be available at several exhibit tables in the North Foyer area outside of the Ballroom. Please take a moment to stop by and learn more about their unique offerings for our Community.

GET CONNECTED

Wireless Network: **MARRIOTT_CONF**
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@U2FP_W2W

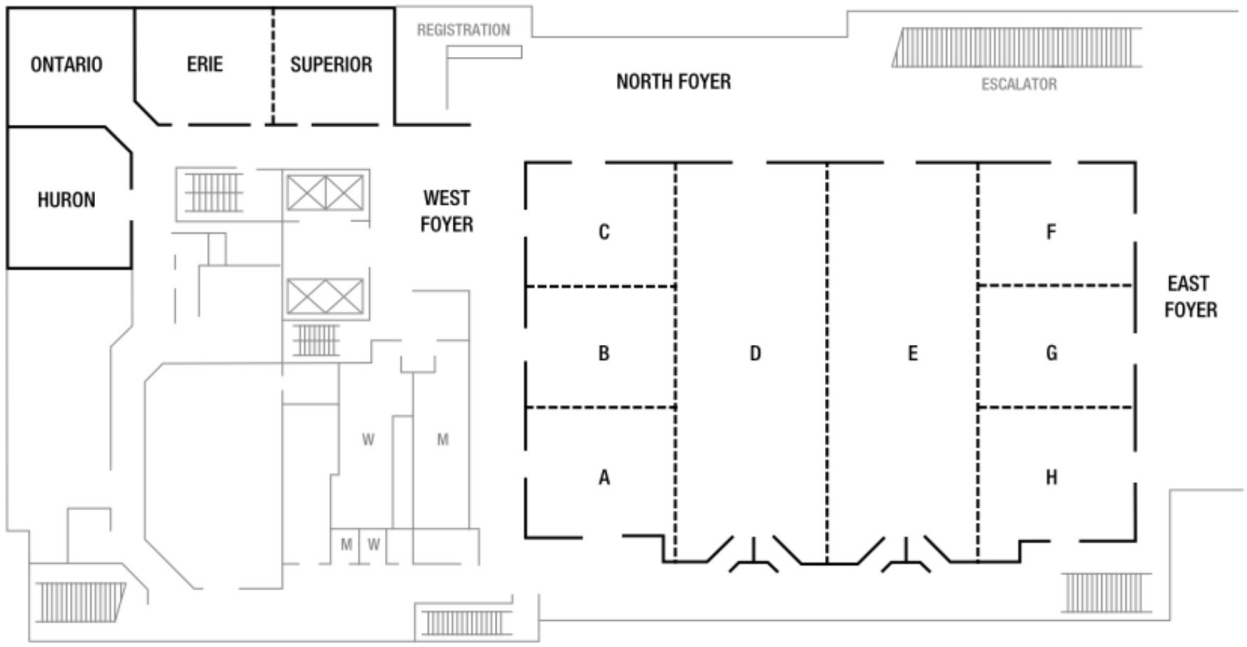
ACCESSIBLE BATHROOMS

Please note the location of accessible bathrooms on the Marriott map (opposite page) in the West Foyer near the elevators.

A WELCOMING SPACE

Unite 2 Fight Paralysis is committed to creating a welcoming event. We seek to create an environment where everyone feels encouraged to participate. Please help us to nurture a space where we all feel included and where civility grows. Be sure to let the U2FP staff know if you hear or see anything that needs our attention. Thank you!

MEETING ROOM



SPEAKER **BIOS**

A first-class line up of presenters from across the Scientific & Advocacy communities

Mike Alpert | *President/ CEO, The Claremont Club*

Mike Alpert has been the President/CEO of The Claremont Club since 1997. Located in Claremont, California, The Claremont Club is a multi-use athletic, aquatic, tennis & social facility encompassing 19 acres, with a staff of 271 and servicing over 10,400 members. During his time in Claremont he has created a dedicated team with a sense of ownership and accountability; developed a club culture of a passionate and value-based entity and created a focus on making a difference in people's lives. Mike has served on the Northwest Athletic Club Association Board of Directors and is a Past President & Board Member of California Clubs of Distinction. He is also an Advisory Board Member of the Medical Wellness Association. Because his passion is for the chronically injured and the chronically ill, Mike has been presenting "Exercise is Medicine" to universities and organizations internationally. He believes that now, more than ever, the health care industry and the fitness industry must join efforts in combating and preventing the progression of disease and the effects of injury.

Kim Anderson, PhD | *Professor, Department of Physical Medicine and Rehabilitation at the MetroHealth Medical Center and Case Western Reserve University (CWRU) School of Medicine; Associate Director, Institute for Functional Restoration*

Dr. Anderson-Erisman is a Professor in the Department of Physical Medicine and Rehabilitation at the MetroHealth Medical Center and Case Western Reserve University (CWRU) School of Medicine, and Associate Director of the Institute for Functional Restoration. She also has lived with a cervical spinal cord injury for 30 years. Her research focuses on translational investigations and bridging the gap between basic science, clinical science, and the public community living with spinal cord injury (SCI). At MetroHealth-CWRU she is continuing her involvement in clinical trials with the team pursuing implanted stimulation devices for SCI and further developing her independent research efforts addressing issues important to people living with SCI with an emphasis on translational research to deploy treatments to the clinic.

Matthew Bellman, PhD | *Co-Founder & Chief Technology Officer, Myolyn*

Matthew Bellman, PhD, received his bachelor's, master's, and doctoral degrees in mechanical engineering from the University of Florida. Dr. Bellman joined the Nonlinear Controls and Robotics group as an undergraduate and continued research with the group throughout his graduate career. His research interests revolve around human movement and include robotic exoskeletons, high performance prosthetics, and functional electrical stimulation (FES). His doctoral dissertation was focused on the control of human muscle via FES for the purpose of rehabilitating people with paralysis. Now, Dr. Bellman is the co-founder and Chief Technology Officer of MYOLYN, a medical technology company that combines robotics and electrical stimulation to improve health and human performance, where he is responsible for product development, quality management, and regulatory affairs.

Jeni Belt | *Cure Advocacy Network – Ohio*

Jeni Belt is an attorney, activist and one of the founding members of SCI Connect, a Northwest Ohio community-based support network whose members include individuals with spinal cord injuries and other conditions which limit mobility. She helped SCI Connect to partner with U2FP to launch Ohio's Cure Advocacy Network (CAN) after attending Working 2 Walk 2016 in Minneapolis. Ohio recently passed a $3 million research bill for spinal cord injury research following the model established by U2FP and Get Up Stand Up 2 Cure Paralysis in Minnesota due to the advocacy efforts of CAN. Her personal connection to the spinal cord injury community comes from her best friend, Jason, who sustained a spinal cord injury while they were on vacation in 2016 and from the many friends in chairs she and Jason have met as a result.

Ian Burkhart | *FES/Stim Participant Panel*

Ian Burkhart sustained a spinal cord injury in 2010 on a beach vacation celebrating the end of his freshman year of college. After learning his diagnosis of a quadriplegic and undergoing intensive rehabilitation, he was ready to rebuild his life. Since then he has participated in a neural bridging research study by having a brain implant surgery as part of the clinical trial, Reanimation in Tetraplegia, through The Ohio State University Wexner Medical Center and the Battelle Memorial Institute, a groundbreaking study that has enabled Ian as a quadriplegic to move a paralyzed limb for the first time. Ian is pursuing a business degree at Ohio State University. As a part of his commitment to making life easier for individuals with spinal cord injuries, he created the Ian Burkhart Foundation in 2017 which is dedicated to restoring lives and providing hope to individuals with spinal cord injuries. He is a Christopher Reeve Foundation peer mentor and advocates for legislation to fund spinal cord injury research in the state of Ohio. Ian also is a national public speaker sharing his story of hope, perseverance, and triumph through tragedy.

Jake Chalfin | *Cure Advocacy Network – Pennsylvania*

Jake Chalfin sustained a spinal cord injury in a steeplechase horse racing accident in 2010. Not to be slowed down he married in 2015 and had a son born in 2018. Jake and his wife subscribe to the school of thought that for numerous reasons too many to count, that curative treatments for SCI will be the most productive benefit of research and development efforts greatly improving the health and well-being of all individuals in our community. Armed with this strong belief and supported by U2FP, Jake was part of a small group of advocates that successfully lobbied for a bill that will provide state funding in Pennsylvania for SCI research.

David Darrow, MD, MPH | *Chief Neurosurgery Resident, University of Minnesota; Principal Investigator, E-STAND Clinical trial*

Dr. David Darrow is the chief neurosurgery resident at the University of Minnesota and is the PI for the E-STAND Clinical trial. Dr. Darrow is interested in functional neurosurgery and the treatment of functional diseases of the central nervous system including epilepsy, movement disorders, spinal cord injury, traumatic brain injury, and psychiatric diseases. He is co-PI of the Herman-Darrow Neuromodulation Lab at the University of Minnesota. Through his research, he works directly with biomedical engineers to unify noninvasive and invasive forms of neuromodulation with validated, model-based approaches and control theory. He specializes in clinical trials and the application of novel devices and algorithms to optimize and understand neuromodulation approaches to treating disease.

Marc DePaul, PhD | *Director of Research & NVG-291 Project Leader, NervGen Pharma Corp.*

Dr. DePaul received his PhD from Case Western Reserve University, where his work covered multiple projects exploring different therapies to restore functional recovery after spinal cord injury. The first project used a cell-based, immunemodulatory therapy applied systemically after acute spinal cord injury. A second project aimed to regenerate axons in a chronically injured spinal cord. A third project explored PTPsigma's role in regeneration failure and is the basis for NervGen's regeneration technology. Dr. DePaul served as an advisor for Oregon Health & Science University's development of a preclinical spinal cord injury model to explore therapeutic treatments of traumatic SCI, and as a scientist at Neurona Therapeutics prior to his role at NervGen Pharma.

Kym Eisner, BA, MFA, MNPM | *Executive Director, Craig H. Neilsen Foundation*

Kym Eisner is the Executive Director of the Craig H. Neilsen Foundation, the largest private funder in the U.S and Canada dedicated to supporting both programs and scientific research to improve the quality of life for those affected by and living

with spinal cord injury. Kym joined the Foundation in 2014 with more than 25 years of experience in philanthropy and the non-profit sector. Prior to her work in the scientific and disability communities, she worked with both emerging and established non-profits as well as serving on numerous boards focusing on education, social services, health system infrastructure development and the arts.

Jen French |

FES/Stim Participant Panel

As a result of a snowboarding accident, Jennifer French became a quadriplegic due to a spinal cord injury in 1998. She is an active user of the Implantable Stand & Transfer System provided by the Cleveland FES Center, MetroHealth Medical Center and Veterans Administration; and the first woman to receive such a system. As a user of neurotechnology who has reaped its benefits, she is the Co-founder and Executive Director of a 501(c)(3) non-profit organization, Neurotech Network which focuses on education and advocacy regarding neurotechnology. Jennifer has been featured in several media outlets and is an accomplished writer and speaker who has addressed organizations, such as the National Academy of Sciences, the World Science Festival, TEDx Talks, the NIH/NINDS Neural Interfaces, General Electric and many more. French is also the Associate Publisher and Senior Editor of Neurotech Reports, a leading news publication and market analysis firm for the neurotechnology industry.

Alina Garbuzov |

Postdoctoral Researcher, University of California, San Diego - School of Medicine

Alina is a post-doctoral researcher in the lab of Mark Tuszynski at the Center of Neural Repair at UCSD Medical School. She attended Brown University for her undergraduate degree, where she studied Neuroscience and Molecular Biology. After Brown, she moved to California to attend Stanford Graduate School. During her PhD studies she fell while rock climbing and fractured her L1 vertebra. Alina was able to re-start school and complete her dissertation in the field of stem cell biology and genetics. She brings expertise in molecular biology, stem cell biology, and bioinformatics to a lab that specializes in stem-cell based treatment for SCI.

Hal Hargrave | *Founder, Educational & Marketing Director, The Perfect Step*

Hal Hargrave is the owner and founder of The Perfect Step and presently serves a role as the Facilities Manager as well as the Educational and Marketing Director. Hal became a part of the team back in 2007, shortly after he sustained a spinal cord injury in an auto accident. Hal was approached by Mike Alpert and the Claremont Club, in an effort to try and provide treatment to Hal and be a part of his ongoing therapy regiment and recovery. What started in a small converted racquetball court for paralysis recovery, has now transpired into something far greater than what both Hal and Mike probably ever anticipated. With a now 7000 square-foot facility, which treats many different neurological ailments and illnesses, The Perfect Step, the Claremont community, The Claremont Club, the Hargrave family and Mike Alpert are making a tremendous impact in the lives of many. Hal hopes that with his collaboration with The Claremont Club and Mike Alpert, that they be able to take The Perfect Step nationwide and provide services of paralysis recovery to every major region of the United States.

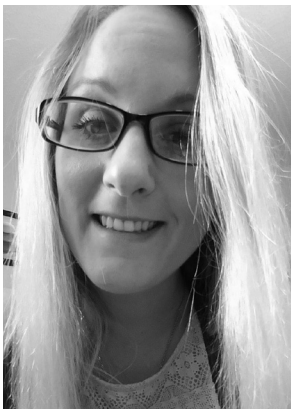
Jessica Kwok | *Associate Professor, Faculty of Biological Sciences, University of Leeds, Leeds, UK; Institute of Experimental Medicine CAS, Prague, Czech Republic*

Jessica Kwok is an Associate Professor at the University of Leeds (United Kingdom). She was trained as a glyco-/neuro-scientist. Her research focuses on modulating the extracellular matrix environment in the central nervous system to enhance plasticity and regeneration after injury. Dr. Kwok received her Ph.D. at the University of Hong Kong investigating the role of chondroitin sulphate proteoglycans (CSPGs) in neural development. She then moved to the University of Cambridge for her postdoctoral work before joining the University of Leeds. There, she elucidated the hierarchical assembly of perineuronal nets and how this extracellular matrix assembly regulates neuroplasticity. She aims to combine her knowledge in CSPGs and neuroplasticity in designing new tools for enhancing functional recovery after spinal cord injury.

Michael Lane, PhD |

Associate Professor, Drexel University – School of Medicine

Michael began research in spinal cord injury during his undergraduate research at the University of Tasmania. After graduating with a Bachelor of Science (Hons), Michael completed his PhD with Norman Saunders at the University of Melbourne. In 2005, he began postdoctoral training at the Universities of Melbourne and Florida (with David Howells and Paul Reier, respectively), before accepting a non-tenure track position at the University of Florida in 2009. After receiving funding from the National Institute of Health (R01) in 2012, Michael accepted a position with the Spinal Cord Research Center at Drexel University to continue his research into spinal cord injury, neuroplasticity and strategies to optimize repair and lasting functional recovery. Now an Associate Professor, funded by the NIH and research foundations, Michael is actively pursuing cell therapies and rehabilitative strategies to promote recovery of breathing after cervical spinal cord injury.



Allie Leatherman |

Cure Advocacy Network – Ohio

I'm Allie, 32 years old, from Northwood, OH. After a car accident in July 2014, I became a C 6/7 quadriplegic. The wind in my sails returned as I became involved in a grassroots advocacy group called SCI Connect in Toledo a year or 2 after. The game changer! Since then, I've embraced as much as I can. Still an avid concert goer, lover of life, people, nature & most things furry with more of a social life than ever before! When my service dog, Taylor, and I aren't out on adventures I can be found reading, writing or talking to myself outside. I was recently accepted into the epidural stimulator trial in Louisville through Dr. Harkema and plan on relocating to Kentucky this fall.

John H. Martin, MD |

Medical Professor, CUNY School of Medicine

Dr. John (Jack) Martin is a Medical Professor at the City University of New York School of Medicine and is an internationally-recognized neuroscience researcher. He is also the founder of the Neural Development and Repair Research Cluster that is housed in the City College of New York's Center for Discovery and Innovation. Dr. Martin's research is devoted to finding ways to improve function in people with mobility impairments, through advancing novel neuromodulation-based treatments. His laboratory uses animal models to study the brain and spinal cord neural circuits for movement and how they respond to a spinal cord injury. A major current effort of his lab is a research project to translate an effective brain and spinal cord neuromodulation approach in the rodent to the human. Dr. Martin's research is currently supported by the NIH, Craig Nielsen Foundation, PVA, and the New York State Department of Health Spinal Cord Injury Research Board. http://martinlab.ccny.cuny.edu/

Rebecca Martin, OTR/L, OTD, CPAM |

Manager, Clinical Education and Training, International Center for Spinal Cord Injury (ICSCI), Kennedy Krieger Institute

Dr. Rebecca Martin is the Manager of Clinical Education and Training at the International Center for Spinal Cord Injury (ICSCI) at Kennedy Krieger Institute and an Assistant Professor at The Johns Hopkins University School of Medicine in the Department of Physical Medicine and Rehabilitation. Dr. Martin received her Bachelors of Science in Occupational Therapy from Boston University in 2001 and her Occupational Therapy Doctorate from Rocky Mountain University of Allied Health Professions in 2008. As the Manager of Clinical Education and Training at ICSCI she is responsible for program development, staff training, and oversight of the clinical research program. Dr. Martin speaks nationally on topics related to Activity-Based Rehabilitation. She has been the principal investigator and co-investigator for grants to develop, promote, and disseminate an activity-based therapy training curriculum and investigate novel applications of electrical stimulation for the restoration of function lost to SCI.

Dana McTigue, PhD |

Professor and Vice Chair of Research in the Department of Neuroscience and in the Center for Brain and Spinal Cord Repair, Ohio State University

Dr. McTigue is Professor and Vice Chair for Research in the Department of Neuroscience at Ohio State University. She received her BS in Biology from Pennsylvania State University and her PhD in Physiology from Ohio State University in 1995. She stayed at OSU for a postdoc and was offered a faculty position in the Department of Neuroscience there in 2003. She has a long track record of studying endogenous repair mechanisms after

spinal cord injury (SCI), with a particular emphasis on oligodendrocyte progenitor cells. She has more recently developed a new research direction that focuses on pathological systemic effects of SCI that lead to meta-inflammation and metabolic disease. In particular, her work is focusing on the effect of SCI on liver function and pathology and how this contributes to overall metabolic Disruption.

Susan Miller, MD |

Coverage and Analysis Group, Centers for Medicare and Medicaid Services

Dr. Susan Miller is a Board Certified physiatrist. For the last 12 years she has been a member of the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services (CMS). Before joining CMS , she practiced across a spectrum of acute as well as post- acute care sites, in both academic and community settings located in and around Cleveland, Tampa and Washington, DC.

Megan Moynahan, MS |

Executive Director, Institute for Functional Restoration

Megan Moynahan is the Executive Director of the Institute for Functional Restoration, a non-profit organization based at Case Western Reserve University in Cleveland OH, that has the mission to restore function to people with spinal cord injury by building a sustainable commercial enterprise for neuromodulation systems. The IFR's unique commercialization approach assures the steady translation of proven technologies out of research and into stable commercial availability. The IFR is currently shepherding a multi-function neuroprosthetic system through the regulatory and commercialization stages, with support from both philanthropy and traditional grants. Prior to this, Megan enjoyed a 17-year career at the US Food and Drug Administration's Center for Devices and Radiological Health, where she served as its Associate Director for Technology and Innovation, leading a variety of projects including directing the White House sponsored Entrepreneurs-in-Residence program at FDA, and the Innovation Pathway program designed to streamline the regulatory process for innovative medical devices. She holds a BS in Biomedical Engineering from Johns Hopkins University and a MS in Biomedical Engineering from Case Western Reserve University.

Laszlo Nagy | *FES/Stim Participant Panel*

On June 24, 2002, Laszlo was extensively injured in a motorcycle accident. The most significant and lasting injury was a Spinal Cord Injury (SCI) at the C-3/C-4 level. Laszlo spent nearly a month in the ICU and step down ICU at Northwestern Memorial Hospital. After discharge, Laszlo spent a little over two months at the Rehabilitation Institute of Chicago. From Chicago, he returned back to Cleveland, his hometown, and resided at the Aristocrat Berea nursing home. On June 25, 2003, Laszlo was the recipient of the Synapse Biomedical diaphragm pacer as part of the original FDA investigational grant. Laszlo has been living with the diaphragm pacer till this day.

Peter Nowell |

Cure Advocacy Network – Ohio

Peter Nowell sustained a C4/5 incomplete spinal cord injury in 2005 as a result of a motorcycle accident. He completed his rehab at OSU Wexner Medical Center, slowly getting back to walking with a cane and driving with normal foot controls after about 12 months. Previously a Plant Manager for a plastics extrusion factory, Peter changed careers to become a cost reduction consultant for 10 years, but now dedicates his time to SCI advocacy work. About 4 years ago Peter became a certified peer mentor with the Christopher and Dana Reeve Foundation and started the central Ohio SCI Peer Mentor program with OSU and has mentored over 40 patients. Peter likes to travel with his wife and has had the opportunity to try many new activities since his accident; kayaking, using a snow ski-bike, hang gliding and sitting in with fellow SCI patients in race and rally cars, and most recently a dune buggy adventure.

Ann M. Parr, MD, PhD |

Assistant Professor, Department of Neurosurgery, University of Minnesota

Dr. Parr is a Board Certified Neurosurgeon and interested in finding new therapies for spinal cord injury. She completed her PhD studies in neural stem cell transplantation for spinal cord injury during neurosurgical residency at the University of Toronto. After her training Dr. Parr came to the University of Minnesota where she is currently an Associate Professor in the Department of Neurosurgery, as well as the Medical Director for Spine and Principal Investigator of the Parr Lab at the

Stem Cell Institute. She is Past-Chair of both the Minnesota Neurosurgical Society and the Section for Women in Neurosurgery. Dr. Parr's research centers on transplanting neural stem cells grown from a patient's own skin into the injured spinal cord. She has an active translational research laboratory, and is interested in examining mechanisms of functional recovery using techniques such as histology and immunohistochemistry, cell culture, optogenetics and animal modeling.

P. Hunter Peckham, PhD |

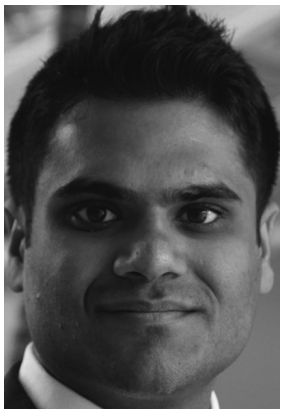
Donnell Institute Professor of Biomedical Engineering and Orthopaedics, Distinguished University Professor, Founder, Institute for Functional Restoration at Case Western Reserve University; Associate Director of Technology Transfer, Cleveland FES Center of Excellence, Department of Veterans Affairs; Co-Director, MetroHealth Rehabilitation Institute at MetroHealth Medical Center

The Institute for Functional Restoration, or IFR, at Case Western Reserve University (CWRU) deploys neuroprosthetic interventions into clinical use to restore the functions lost due to spinal cord injury or other paralytic conditions. The IFR acts as the surrogate corporate partner for the neural technologies that have demonstrated feasible within the research programs. Dr. Peckham is also the NINDS CREATE award recipient for evaluating the feasibility of a pivotal clinical trial for the implementation of the Networked Neuroprosthesis to restore hand function in people with spinal cord injury. The major area of Dr. Peckham's research is in rehabilitation engineering and neuroprostheses. Dr. Peckham's research effort focuses on functional restoration of the paralyzed upper extremity in individuals with spinal cord injury. He and collaborators developed a number of implantable neural prostheses which utilize electrical stimulation to control neuromuscular activation. They have implemented procedures to provide upper extremity control in individuals with tetraplegia, enabling individuals with central nervous system disability to regain the ability to perform essential activities of daily living. His present efforts concern technology development, expansion of the indications for this technology, and technology transfer. Dr. Peckham is a fellow of the American Institute of Medical and Biological Engineering; a fellow and honorary member of the American Spinal Injury Association; member of the National Academy of Engineering; and a member of the National Academy of Inventors. He is a member of numerous professional organizations. Dr. Peckham received the Paul B. Magnuson Award, the highest honor for VA Rehabilitation Investigators. He received his undergraduate degree in Mechanical Engineering from Clarkson College of Technology (now Clarkson University), Potsdam, NY, and his MS and PhD degrees in Biomedical Engineering from Case Western Reserve University.

Vivek Pinto, PhD |

Assistant Director, Division of Neuromodulation and Rehabilitation Devices, Office of Health Technology #5: Neurological and Physical Medicine Devices, Food & Drug Administration

Dr. Vivek Pinto currently serves as an Assistant Director in the Division of Neuromodulation and Rehabilitation Devices in the Office of Health Technology #5: Neurological and Physical Medicine Devices in the FDA. He is currently managing the Acute Injury and Neurodegenerative Device teams. Dr. Pinto earned a B.S. degree in Mechanical Engineering from the University of Pittsburgh and M.S. and Ph.D. degrees in Ergonomics and Biomechanics from New York University. He worked as a mechanical design engineer and a clinical researcher prior to joining the FDA. In 2012, he joined the Agency as a scientific reviewer reviewing electrical stimulators, wheelchairs, exoskeletons, amongst other devices for rehabilitation purposes. Since 2014, he served as a Chief in the Center for Devices and Radiological Health (CDRH) for several different branches. Dr. Pinto regularly provides industry with information to help expedite access of safe and effective rehabilitation devices for individuals with disabilities.



Phillip Popovich, PhD |

Professor and Chair, Department of Neuroscience; Co-Director of the Neuroscience Research Institute; Director of the Center for Brain and Spinal Cord Repair; Faculty Affiliate, Chronic Brain Injury, Ohio State University

Phillip Popovich completed his PhD training in physiology and spinal cord injury (SCI) at Ohio State University (OSU) where he is currently Professor and Chair of Department of Neuroscience, Director of OSU's Center for Brain and Spinal Cord Repair and Executive Director of the Belford Center for Spinal Cord Injury. As a post-doctoral fellow, also at OSU, he was awarded a Sandoz Research Fellowship that supported his formal training in immunology and CNS autoimmune disease. His research program is focused on understanding how SCI disrupts communication between the nervous and immune systems leading to a state of chronic immune dysfunction, including immune suppression and "metainflammation".

David Powers |

FES/Stim Participant Panel

I'm David Powers (59 years old) and I was injured on July 4, 2013 in a motorcycle accident. My initial diagnosis was a C2, C3 but it's now upgraded to C5 through therapy. I had averaged Bacterial Pneumonia twice a year which caused me to have respiratory issues or failure and extended hospital stays. I learned about the FES program from a poster on a door. They were trying diaphragm stimulators to assist persons with para or quad injuries with respiratory issues to improve breathing and cough assist. I received my implant in August 2017 and was taught how to use it in a very short time. Since then my cough with my stimulator can expel excretions, food particles or choking issues with relative ease and I have had no respiratory infections or pneumonias. To say the stimulator has improved my lifestyle and my peace of mind would be an understatement. Now I can do things such as travel, take my wheelchair places and eat with or without a caregiver. My breathing is easier and my cough is strong enough to expel most things even without using my stimulator. So when asked about the device, I have to give it high praise and recommend it for anyone with respiratory issues.

Jason Shaw |

FES/Stim Participant Panel

Jason Shaw was born June 1, 1974 and is from Cleveland, Ohio. Jason has a Vocare bladder and bowel system and has had an implant since 2003.

Jerry Silver, PhD |

Professor, Department of Neurosciences, Case Western Reserve University - School of Medicine

Dr. Silver received his PhD from Case Western Reserve and was the recipient of the Herbert Steuer Memorial Award for Meritorious Original Research in Anatomy. He did post-doctoral work at Harvard University. Dr. Silver is currently Professor in the Department of Neurosciences at the Case Western Reserve University School of Medicine. Dr. Silver is a recipient of several prestigious awards including the Ameritec Prize, the Christopher Reeve-Joan Irvine Research Medal, a Jacob Javits Neuroscience Investigator Award and the Erica Nader Award. He is a fellow of the American Association for the Advancement of Science. Dr. Silver has served on a number of editorial boards and he reviews grants for many national and international organizations. He has served on a variety of NIH study sections and he has been appointed as a regular member of the Scientific Board of the International Spinal Research Trust. He has more than 180 publications.

Maria Sutter |

FES/Stim Participant Panel

My name is Maria Sutter. I've been thriving as a woman with a spinal cord injury and tetraplegia for 15 years. Since my injury, I've utilized my skills, aptitude and determination to care for myself and impact others. I've participated in traditional rehabilitation, self-directed exercise, personal training at a spinal cord focused wellness center, elective procedures to regain neuro-muscular function, and FES research and implantation. I've completed a Master of Arts in Humanities, specializing in Disability Studies, from John Carroll University. I've had the pleasure of working with a Cleveland based non-profit organization creating educational seminars and presentations that provide individuals with disabilities assistance navigating their unique needs for daily living. I've also spoke with large and small audiences of clinicians, researchers, policy makers, and peers to connect them with the enriched - though often misconceived or marginalized - experiences and perspectives of a person with a disability whose life is flourishing.

Lynn Wolf |

FES/Stim Participant Panel

My name is Lynn Wolf. I live in Minneapolis, MN. While on spring break vacation 9.5 years ago, I was in a skiing accident. I broke a lot of things including but not limited to shattering my skull and breaking my back in 5 places. After 1.5 years of in-patient rehabilitation, I completed my Master of Science degree in Chemical Engineering. Right now I work as security for the Minnesota Vikings football team. I am looking to go back to school to finish my Ph.D., a venture that was interrupted after I was injured. In my free time I love playing wheelchair sports. I play competitive softball with the Minnesota Flamethrowers and tennis and basketball for fun. I also love coaching kids basketball and softball. In May of 2018 I had an epidural stimulation device implanted. I participate in Activity Based Locomotor Exercise (ABLE) three times a week where an exercise program is tailored for me. I have no doubt that my participation in ABLE, in conjunction with the stimulator, has helped in my journey to be able to stand and possibly walk on my own again.

Ernest Wong, PhD |

President, CEO & Director, NervGen Pharma Corp.

Ernest Wong has over 20 years of experience in the pharmaceutical and biotechnology industries. Prior to joining NervGen, Dr. Wong was the Vice President, Corporate Development of Accera, Inc., a Nestle Health Science backed clinical stage biotechnology company that develops therapies for central nervous system disorders. Prior to Accera, Dr. Wong was the Head of Business Development and Licensing at Piramal Imaging where he successfully completed a number of high-value strategic transactions as part of the commercial launch of a neuroimaging agent. Prior to Piramal Imaging, he led the corporate development function at YM Biosciences where he executed a partnering campaign for a phase 2/3 product that resulted in the acquisition of the company by Gilead for over $500M. His experiences also include executing business development transactions, managing partnerships and global clinical programs at OSI Pharmaceuticals and AnorMED Inc.

Lyandysha Zholudeva |

Postdoctoral Researcher, Drexel University College of Medicine

Lyandysha (Lana) Zholudeva completed her Bachelor of Science in Chemistry with a Minor in Biophysics at Creighton University, where she worked on developing non-invasive imaging techniques for quantifying cellular metabolism. Lana recently completed her doctoral work with Dr. Michael Lane in the Department of Neurobiology & Anatomy at Drexel University College of Medicine and has continued on as a postdoctoral fellow. The goal of her work is to transplant neural progenitor cells to repair the injured cervical spinal cord, with a focus on improving respiratory function. Her research aims to identify specific subsets of neural precursors that are most effective for promoting spinal cord repair, and assessing whether combining transplantation with rehabilitation improves donor-host integration and functional improvement.

SPEAKER Abstracts

EXERCISE IS MEDICINE: HOW TO REDUCE SECONDARY COMPLICATIONS AND INCREASE QUALITY OF LIFE OUTCOMES FOR INDIVIDUALS WITH SPINAL CORD INJURY

Mike Alpert | President/CEO, The Claremont Club
Hal Hargrave | Founder, Educational & Marketing Director, The Perfect Step

The Perfect Step at The Claremont Club is a renowned paralysis recovery center located in Southern California. Our staff has more than 45,000 hours of experience and a facility that has amassed more than 80,000 client hours in its 12-year history. This experience has presented an opportunity for the facility, our leadership staff, and our group of specialists to explore creative benchmarks that have led to an effective program for those living with spinal cord injuries. Not only are we believers in the notion that exercise is the most powerful form of medicine in the world, but we believe that our methodology and our recovery approach is physically, mentally and emotionally beneficial for those living with spinal cord injuries. However, it is one thing for us to talk about it, but it is another thing to provide empirical data that answers these very questions.

We have a firm belief that our program not only provides physical recovery, but it also reduces the susceptibility to secondary complications in our spinal cord injured clients and provides an opportunity at a better quality of life. Through our copyrighted methodology, the "S.T.E.P. Method©", and our approach towards table work (Patterned Neural Activity Recruitment©), loadbearing, and the incorporation of exercise, we believe that we are giving our clients the best shot at recovery. Our current IRB approved study, in partnership with Kaiser Permanente (in Fontana, California) and Doctor Robert Salas, is revealing these positive outcomes relating to increased quality of life and decreased secondary complications – measures that prove the effectiveness of our program in the lives of those living with spinal cord injury. This multi-year study is currently finishing up its first year which is conducted in survey form. 45 of our spinal cord injured clients have responded candidly to the survey, and are indicating the positive effect that the program is having on their lives.

With this data we hope to be able to present our findings in the near future to insurance companies to get third-party reimbursement. We also hope to present it at the governmental level to achieve reform for programs like ours. It is our hope that similar outpatient exercise and activity-based therapy programs are able to get more visibility because of their positive outcomes, rather than constant scrutiny because of perceived lack of credibility of non-licensed therapists. This is simply a matter of strength in numbers: the more facilities that we can get in our corner to obtain important data like this, the more we will be able to turn heads to make a real difference.

EPIDURAL SPINAL CORD STIMULATION FOR SPINAL CORD INJURY: E-STAND UPDATE

David Darrow, MD, MPH | Chief Neurosurgery Resident, University of Minnesota; Principal Investigator, E-STAND Clinical trial

Stimulation of the spinal cord and nerve roots from the epidural space (epidural spinal cord stimulation) has generated great interest for the treatment of chronic thoracic spinal cord injury. Surgical implantation of an epidural stimulation system is performed as an outpatient procedure and takes approximately 90 minutes. Funded by the state of Minnesota with devices supplied by Abbott (St. Jude Medical), the E-STAND trial is a phase I and II clinical trial designed to test and optimize the effect of surgically-implanted epidural spinal cord stimulation for the treatment of motor-complete (AIS A/B) chronic SCI to restore volitional movement and autonomic function. The E-STAND trial has enrolled and implanted 12 patients after screening more than 30 and prescreening more than 900. Quantitative assessment of volitional movement and autonomic function has demonstrated large improvements from baseline in restoration of movement, blood pressure, cerebral blood flow, cognition, bowel and bladder function as well as reports of improved sexual function. Over time significant improvements in volitional movement have been found to be sustained in some patients even when stimulation is ceased. Epidural stimulation has also been found to restore the ability to volitionally pedal a bicycle and improve transferring ability. Computational modeling and stimulation mapping have allowed us to better understand where and how to place stimulators. Our team's novel optimization platform has demonstrated that significant preferences for certain parameters exist across patients in a fairly tight range of frequency. While some evidence exists to support a mechanism due to changes in excitatory/inhibitory circuitry locally in the segments of the spinal cord from indirect neuromodulation, there remains great uncertainty due to the difficulty of measuring signals in the spinal cord. In our study, an existing commercially-available system is used providing a pathway for rapid translation with a well-characterized safety profile. Further studies are required to formalize specific clinical targets and obtain FDA approval for use in SCI.

PROTEIN TYROSINE PHOSPHATASE INHIBITORS FOR SPINAL CORD INJURY THERAPY

Marc DePaul, PhD | Director of Research & NVG-291 Project Leader, NervGen Pharma Corp.

Recovery from spinal cord injury (SCI) is limited due to the inhibition of neural regeneration and functional plasticity. Upregulation of chondroitin sulphate proteoglycans (CSPGs) within the glial scar and perineuronal net creates a barrier to axonal regrowth and sprouting as well as oligodendrocyte remyelination. The neural receptor protein tyrosine phosphatase sigma (PTPσ) has been identified as the predominant receptor and mediator of CSPG mediated inhibition of neural recovery. The prototype PTPσ inhibitor known as intracellular sigma peptide (ISP) has shown a remarkable ability to alleviate or improve the symptoms and conditions associated with SCI in preclinical models. Inhibition of PTPσ with systemic ISP treatment substantially improves nerve function by promoting regeneration of damaged axons, sprouting of spared nerve tracts and the remyelination of demyelinated regions.

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This has facilitated functional recovery of key bodily functions including locomotor and urinary systems. Building on the promise observed in preclinical studies, NervGen plans to initiate a Phase 1 human trial in 2020 with a close analog of ISP called NVG-291. NVG-291 potentially represents the first-in-class PTPσ inhibitor to enter clinical development for SCI therapy. With NVG-291 and its novel PTPσ inhibitory approach to treating SCI, NervGen strives to restore life's potential to SCI patients by promoting neural regeneration, which hopefully will allow patients to live more active and productive lives.

NEURAL STEM CELL GRAFTS AS TREATMENT FOR SPINAL CORD INJURY

Alina Garbuzov | Postdoctoral Researcher, University of California, San Diego - School of Medicine

The Tuszynski lab develops neural stem cell grafts that improve functional recovery in rodent and non-human primate models of spinal cord injury. Neural progenitor cells (NPCs) and human embryonic stem cells directed to take on a spinal cord neural stem cell identity, when grafted into spinal cord lesions, form a functional neural relay connecting the spinal cord areas below and above the lesion site. Our recent work shows successful engraftment of human spinal cord–derived multipotent neural progenitor cells into rhesus monkeys after C7 lesion, resulting in improvement to skilled hand function. To determine if the NPC graft approach is an appropriate treatment for chronic spinal cord injury, our latest study involves testing the therapeutic potential of NPCs in rats well after the recovery period, once the injury has fully stabilized. The goal of our work is the application of neural progenitor grafts as a treatment for both acute and chronic SCI.

Team Members: Paul Lu, Hiromi Kumamaru, Ephron S Rosenzweig, Ken Kadoya, Alina Garbuzov and Mark H Tuszynski

Funding Sources: NIH, CIRM, Veterans Administration

Publications:

https://www.nature.com/articles/nm.4066
https://www.nature.com/articles/s41592-018-0074-3
https://www.nature.com/articles/nm.4502

NON-INVASIVE TREATMENT FOR FUNCTIONAL RECOVERY AFTER THE SPINAL CORD INJURY

Jessica Kwok, PhD | Associate Professor, University of Leeds (United Kingdom)

After spinal cord injury, there is a strong upregulation of neural inhibitory molecules around the lesion scar preventing regeneration and neuroplasticity. One of the key molecules is chondroitin sulphate proteoglycans (CSPGs). In addition to their presence at the lesion site, CSPGs are also present in perineuronal nets (PNNs) under normal physiological condition. PNNs are dense pericellular structures that envelop sub-populations of neurons throughout the central nervous system providing stabilisation of circuitry and thus regulation of plasticity. To enhance recovery

after spinal cord injury, therapies aim to promote regeneration of severed axons and the plasticity of surviving circuitry. Enzymatic removal of CSPGs using chondroitinase ABC (ChABC) opens a window of plasticity enhancing functional recovery, particularly in spinal cord injury models. However, there are significant hurdles translating ChABC into clinical use due to its bacterial enzymatic nature.

We have recently repurposed a small molecule, perineuronal net inhibitor (PNNi), which provides a non-invasive strategy in down-regulating CSPGs in the CNS. Daily oral administration of PNNi successfully down-regulates CSPGs in the injured spinal cords and PNNs in rodents. This downregulation enhances the recovery of hindlimb functions when combined with rehabilitation. We are currently exploiting the use of PNNi in enhancing recovery in chronic spinal cord injury.

Team Members: Sian Irvine [1], Sylvain Gigout[1] and Jessica Kwok [1,2]
[1] Faculty of Biological Sciences, University of Leeds, Leeds, UK
[2] Institute of Experimental Medicine, Czech Academy of Science, Prague, Czech Republic
Funding Sources: International Spinal Research Trust, Wings for Life, Medical Research Council

THE NEUROBIOLOGICAL EFFECTS OF STIMULATING THE NERVOUS SYSTEM AFTER SPINAL CORD INJURY

John H. Martin, PhD | Medical Professor, City University of New York School of Medicine

The problem my laboratory addresses is to promote motor function after a spinal cord injury (SCI). We focus on repair of the corticospinal tract, which is the nerve pathway that is most important for voluntary movements. The corticospinal tract originates in the motor cortex of the brain and communicates with spinal cord motor circuits. SCI damages the corticospinal tract and, in consequence, disconnects the motor cortex, where voluntary movements are initiated, with the spinal cord motor circuits, where movements are executed. After injury, the loss of voluntary movement control is largely attributable to the loss of the corticospinal tract's connections.

Most SCIs are incomplete, leaving some corticospinal tract connections spared. Our approach is to promote the function of the spared corticospinal tract connections. We discovered that the activity of corticospinal tract nerve cells after injury is important for making new connections and that these new connections help animals to recover movement functions. We promote activity using non-invasive or minimally-invasive electrical stimulation. We use non-invasive direct current stimulation to activate spinal circuits and epidural motor cortex stimulation to activate corticospinal tract neurons. This general stimulation approach is termed neuromodulation. I will discuss how motor cortex stimulation activates a "growth program" in corticospinal tract neurons, enabling them to make new connections. I will also discuss how spinal cord stimulation both strengthens spared connections after SCI as well as protects key spinal cord neurons from degenerating below the injury level.

CONCLUSION. Our results show that stimulation-based approaches, which can be implemented to be non- or minimally-invasive, produce long-lasting structural changes to the corticospinal system and parallel improvement in motor skills after injury. It is time to explore the rules governing the use of stimulation approaches and behavioral rehabilitation to bring these approaches to clinical therapeutic implementation. Neuromodulatory approaches can be translated readily from animals to humans. Neuromodulation can be "strong medicine" when applied appropriately to the damaged nervous system after injury.

Team members:
PHD students: Alzahra Amer [1,2] , John Kalambogias [1,2]
Research staff: Yuqiu Jiang [1] , Weiguo Song [1] , Preston Williams [1] , Lilian Yang [1] , Neela Zareen [1]
Technical staff: Heather Alexander, Daniel Ryan, Michael Smith, Xiuli Wu [1]
[1] Department of Molecular, Cellular, and Biomedical Science, City University of New York School of Medicine at CCNY, New York; [2] Neuroscience Program City University of New York Graduate Center, New York
Funding sources: NIH 5 R01 NS064004 (current year 12); Craig H Nielsen Foundation; Paralyzed Veterans Association; New York State Department of Health Spinal Cord Injury Board; Christopher and Dana Reeve Foundation.

TRANSCUTANEOUS SPINAL CORD STIMULATION AND ACTIVITY-BASED THERAPY: WHAT DOES IT MEAN FOR ME?

Rebecca Martin, OTR/L, OTD, CPAM | Manager, Clinical Education and Training at the International Center for Spinal Cord Injury (ICSCI) at Kennedy Krieger Institute; Assistant Professor, Johns Hopkins University School of Medicine, Department of Physical Medicine and Rehabilitation

Well established scientific evidence demonstrates that activity is essential for the development and repair of the central nervous system, yet traditional rehabilitation approaches lack the intensity necessary to drive neural change. Activity-Based Therapy (ABT) offers high intensity activation of the nervous system to optimize the capacity for recovery, while working to offset the rapid aging and chronic complications that occur as a consequence of neurologic injury. Treatment focus shifts from compensatory training to promotion of restoration of function. Many ABT investigations include treatments of long duration and high intensity, not feasible in clinical settings for chronic patients. Transcutaneous Spinal Cord Stimulation (TSCS) is a non-invasive mechanism to enhance excitation of spinal neural circuitry and represents a promising supplement to existing therapy programs. This increase in spinal excitability may augment ABT and maximize functional outcomes with greater efficiency and durability than other interventions. To date, however, TSCS studies have happened in experimental conditions with varying degrees of associated interventions. The goal of this talk is to discuss the outcomes of clinically relevant TSCS in conjunction with ABT. Results of an 8-week trial, combining TSCS with intensive walking-based therapy for patients with iSCI, will be discussed. Data presented will demonstrate improvements in walking speed

and endurance in response to the intervention, and evidence for translation of the increase in spinal excitation to an improvement in voluntary function. Strategies and pitfalls that surround clinical application of TSCS and ABT will also be outlined, including discussion of non-walking outcomes and potential mechanisms for chronic, complete patients.

SPINAL CORD INJURY CAUSES CHRONIC LIVER PATHOLOGY AND METABOLIC DISRUPTION IN RODENTS

Dana McTigue, PhD | Professor and Vice Chair of Research in the Department of Neuroscience and in the Center for Brain and Spinal Cord Repair, Ohio Statue University

Since the spinal cord innervates all body organs, injury to the spinal cord disrupts systemic homeostasis. This can lead to metabolic problems such as insulin resistance and hyperlipidemia. These two conditions contribute to the development of diabetes and cardiovascular disease, conditions that occur at an elevated rate in the spinal cord injury (SCI) population. Despite the contribution of these conditions to increased mortality in SCI subjects, little preclinical research has focused on them. An organ central metabolic control is the liver. Thus, we tested the hypothesis that SCI causes liver pathology and overall metabolic problems using a preclinical rat mid-thoracic spinal contusion model. Results show that livers accumulated excess fat and become inflamed within 24h post-injury, which is sustained for at least 6 months. The combination of fat accumulation and inflammation is called non-alcoholic steatohepatitis or fatty liver disease. In SCI rats, this was associated with long-term liver damage, insulin resistance, excess adipose accumulation and elevated circulating lipids. Notably, these conditions are indicative of metabolic disease and occur at a higher incidence in the SCI population. Thus, our animal model is mimicking the clinical condition. New data indicating that liver inflammation alters the overall outcome from SCI will be presented and potential mechanisms for SCI-induced liver pathology will be discussed. The long-term implications for this work are that systemic pathology occurs acutely after SCI and likely continues indefinitely. Finding mechanisms causing acute and persistent metabolic disturbances would address several of the issues that lead to reduced longevity in the SCI population, including cardiovascular disease and diabetes.

Team Members: Matthew T. Goodus, PhD and Dana M. McTigue, PhD
Belford Center for Spinal Cord Injury,
Department of Neuroscience, Wexner Medical Center, Ohio State University

Funding Sources: Craig H Neilsen Postdoctoral Fellowship (MTG)

Publications: Sauerbeck AD, Laws JL, Bandaru VVR, Popovich PG, Haughey NJ, McTigue DM Spinal cord injury causes chronic liver pathology in rats. J Neurotrauma, 32: 159-169; 2015 PMID: 25036371. https://www.ncbi.nlm.nih.gov/pubmed/25036371

Goodus M, Sauerbeck A, Popovich PG, Bruno RS, McTigue DM. Dietary green tea extract prevents hepatic iron overload but does not improve chronic hepatic and spinal cord pathology after spinal cord injury in rats. J Neurotrauma, 35: 2872-82; 2018. doi: 10.1089/neu.2018.5771. https://www.ncbi.nlm.nih.gov/pubmed/30084733

SPEAKER Abstracts

COVERAGE 101+

Susan Miller, MD | Coverage and Analysis Group, Centers for Medicare and Medicaid Services

The discussion will focus on various pathways by which Medicare can encourage access to new technologies for its beneficiaries.

REGIONALLY SPECIFIC SPINAL NEURAL PROGENITOR CELLS IN A 3-DIMENSIONAL BIOPRINTED SCAFFOLD: WHY SPECIFICITY MATTERS

Ann M. Parr, MD, PhD | Assistant Professor, Department of Neurosurgery, University of Minnesota

The Problem: While many have focused on therapies for subacute spinal cord injury (SCI), chronic SCI remains an unmet need, with an estimated 288,000 people currently living with chronic SCI in the US. We and others have transplanted non-specific neural stem cells into the injured spinal cord in various animal models and have reported functional recovery. Cell replacement, neuroprotection, modulation of the environment, and remyelination have all been proposed as mechanisms. However it is unlikely that all of these will also be beneficial in chronic SCI, since these patients are outside of the time frame of benefit, and thus new mechanisms such as the establishment of a relay network should be pursued.

The Plan: Therefore, we propose a combinatorial strategy of bioprinting regionally specific spinal Neural Progenitor Cells (sNPCs) in a 3D printed scaffold. Regional specificity is crucial, as evidenced by recent literature and our own experience (i.e. we need to utilize cells that are normally found in the spinal cord rather than the brain). We propose to directly print these cells in precise locations within a patient specific scaffold that fits into the lesion cavity.

The Results: We can now create these human sNPCs directly from a patient's own tissue through the use of induced pluripotent stem cell technology to avoid immune rejection. Our cells can communicate with other cells, a key feature in using them as a relay. Our cells also have the ability to form limited "mini spinal cords" as they regenerate. Printing them into the scaffolds provides protection during transplantation, guidance for regenerating axons, and increased formation of neural networks. This strategy could be a future treatment for chronic SCI, but work still needs to be done in optimizing the scaffold biomaterial and providing evidence to regulatory agencies that this would be safe and effective in humans.

Team Members: Ann M. Parr, Michael C. McAlpine, Nicolas Lavoie, Daeha Joung, Manuel Esguerra
Funding Sources: Minnesota Spinal Cord Injury and Traumatic Brain Injury Research Grant Program, Morton Cure Paralysis Fund, Cure Paralysis Now, Spinal Cord Society
Publications: https://onlinelibrary.wiley.com/doi/abs/10.1002/adfm.201801850, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5802631/

RESTORATION OF FUNCTION WITH IMPLANTED NEUROPROSTHESES

P. Hunter Peckham, PhD | Donnell Institute Professor of Biomedical Engineering and Orthopaedics, Distinguished University Professor, Founder, Institute for Functional Restoration at Case Western Reserve University; Associate Director of Technology Transfer, Cleveland FES Center of Excellence, Department of Veterans Affairs; Co-Director, MetroHealth Rehabilitation Institute at MetroHealth Medical Center

There is a long standing experience in the development of neuroprostheses for restoration of movement, with the objective of restoring function and independence for the user. The fundamental technique is scientifically based, and has been demonstrated to be safe and effective. Sometimes known as functional electrical stimulation, or FES, the use of implantable FES technology enables a fully implanted device to be available to the user with no external components. Neuroprostheses that interface with the peripheral nervous system use electrical pulses to generate controlled firing in the target nerves, resulting activation of the muscle that that nerve innervates. Small electrodes are used to deliver the electrical stimuli, and the strength of the resultant muscle contraction is controlled by the magnitude of the stimulation results in muscles that are completely or partially paralyzed to be used functionally. This technique is reversible, and results in paralyzed muscles that are strengthened by the applied stimulation.

Hundreds of individuals with chronic spinal cord injuries have received neuroprostheses for restoring functions such as hand grasp, arm movement, trunk stability, standing, bladder control, breathing, cough, and walking. The panel which follows will be a demonstration of the various systems by the users themselves discussing the systems that they have, and their experience with them.

The current availability of most of these neuroprostheses is limited to ongoing clinical trials. Only one, the NeuRx DP system for breathing is commercially available, while all of the others are undergoing feasibility studies in human trials. One of the major challenges faced by investigators is in moving these neuroprostheses through pivotal clinical trials that are necessary to achieve regulatory approval that enables commercial sales. One of the reasons that this is difficult is that the commercialization process currently addresses the small SCI population, and this small market is not attractive to companies. With this forefront, Case Western Reserve University has developed a novel commercialization strategy, the Institute for Functional Restoration, to facilitate the commercialization process.

Team Members: Kevin Kilgore, Anne Bryden, Michael Keith, Harry Hoyen, Megan Moynahan, Kyle Chepla, Kimberly Anderson, Gregory Nemunaitis, John Chae

SPEAKER Abstracts

REGULATORY CONSIDERATIONS TO BRING ASSISTIVE AND THERAPEUTIC DEVICES TO THE COMMUNITY: AN FDA STAFF PERSPECTIVE

Vivek Pinto, PhD | Assistant Director, Division of Neuromodulation and Rehabilitation Devices, Office of Health Technology #5: Neurological and Physical Medicine Devices, Food & Drug Administration

FDA regulatory approval/clearance is often needed for medical devices targeted to help individuals living with medical conditions in the U.S. The Center for Devices and Radiological Health (CDRH) is responsible for assuring that patients and providers have timely and continued access to safe, effective, high-quality medical devices. Regulatory decision-making often incorporates a benefit-risk approach which requires an understanding of the potential clinically meaningful benefits for specific patient populations and the level of risk these patient groups are willing to accept. An ongoing challenge is having an understanding of individual stakeholders perspectives. Transparency of CDRH regulatory pathways can help inform sponsors of the pathways to bring these devices to patients. In addition, transparency of several programs and initiatives in CDRH, targeted to better understand patient perspectives, can help patients identify pathways to engage in the regulatory process and help inform CDRH review staff make appropriate decisions based on the best interests of patients. The aim of this discussion is to present the structure of CDRH, regulatory pathways for medical devices, several challenges for premarket submissions, and pathways for patient advocacy groups to get involved in the regulatory process and better educate CDRH review staff. The goal is to bring safer and better adopted medical device interventions to individuals living with spinal cord injuries.

THE GUT MICROBIOME AND SPINAL CORD INJURY

Phillip Popovich, PhD | Professor and Chair, Department of Neuroscience; Co-Director of the Neuroscience Research Institute; Director of the Center for Brain and Spinal Cord Repair; Faculty Affiliate, Chronic Brain Injury, Ohio State University

Area of inquiry: Spinal cord injury (SCI) disrupts the autonomic nervous system (ANS) which impairs communication between the immune and gastrointestinal (GI) systems. Proper neuro-immune-GI cross-talk is needed to control the gut microbiota, i.e., the community of microbes (bacteria, viruses, fungi) that live in the GI tract and are critical for nutrient absorption, digestion, and immunity. These microbes also communicate with the brain and spinal cord through production of neuroactive metabolites and neurotransmitters.

Methodology and Results: Using a mouse model of SCI and various genomic sequencing technologies to map microbial genomes, we measured post-injury changes in the gut microbe composition. We discovered that SCI causes gut dysbiosis or permanent changes in the composition of all gut microbes, which can worsen lesion pathology and impair recovery of motor function.

Mechanism: Chronic gut dysbiosis is likely caused by permanent damage to the ANS (dysautonomia). Indeed, when SCI occurs above T4 spinal level where the primary sympathetic outflow begins, the scope and magnitude of dysau-

tonomia is worse and is associated with greater gut dysbiosis.

Clinical Prospects and Human Applications: Gut dysbiosis also occurs after SCI in humans. Fortunately, it is possible to treat using oral probiotics. In SCI mice, probiotics promote small but consistent improvements in locomotor function. Also, it may be possible to use metagenomic and metabolomic sequencing to measure changes in gut microbes (from stool samples) and microbe-derived metabolites to predict the prevalence or severity of various SCI comorbidities (e.g., immune dysfunction, metabolic disease, fatigue, anxiety). As these metabolites and the genes responsible for their production are identified, it will be feasible to manipulate them to enhance recovery and quality of life after SCI.

Team Members: Phillip G. Popovich [1] , Kristina A. Kigerl [1] , Kylie Zane [2] , Kia Adams [1] , Matthew B. Sullivan [3]

[1] The Belford Center for Spinal Cord Injury and the Center for Brain and Spinal Cord Repair, Department of Neuroscience, Wexner

Medical Center at The Ohio State University

[2] The Ohio State University College of Medicine

[3] Departments of Microbiology, and Civil, Environmental and Geodetic Engineering at The Ohio State University

Publications:

Kigerl, K.A., Mo, X., Wang, L., Yu, Z., Hall, J.C.E., Popovich, P.G., 2016. Gut dysbiosis impairs recovery after spinal cord injury. J. Exp. Med. 213, 2603–2620. https://doi.org/10.1084/jem.20151345

OVERCOMING BARRIERS TO FUNCTIONAL REGENERATION AND PLASTICITY AFTER SCI

Jerry Silver, PhD | Professor, Department of Neurosciences, Case Western Reserve University - School of Medicine

The goal of the Silver lab is to understand the basic biology that underlies regeneration failure in the adult spinal cord and then use this knowledge to develop strategies to overcome the lack of regeneration in order to promote functional repair after spinal cord injury. The Silver lab was among the very first to suggest that overtly growth repulsive environments, whose function during normal development was to actively turn axons away from improper trajectories, might reappear in the injured CNS and block the attempt of severed axons to re-grow. One of the most interesting families of inhibitory extracellular matrix molecules, the chondroitin sulfate proteoglycans (CSPGs), was first discovered by the Silver lab in the early 1990's to be involved in creating such developmental as well as regenerative boundaries. Nearly 2 decades after CSPGs had been implicated in regeneration failure, the first neuronal receptor for CSPGs that mediates the potent growth inhibition was discovered. It is called Receptor Protein Tyrosine Phosphatase Sigma (RPTPσ) and it up-regulates in growth cones at the tips of severed nerve fibers when they encounter CSPGs. The lab has now generated small blocking peptides that release axons from proteoglycan mediated entrapment, allowing them to regenerate or sprout. Behavioral recovery in animal models of paralysis after administration of the peptide is especially impressive, presenting a potential new avenue for non-invasive treatment for spinal cord injury. We are now entering an era where strategies for providing functional benefit in animal models of spinal cord injury are sufficiently robust that there should be optimism for translational success and, indeed, this peptide has been licensed by NervGen Pharma in order to move this potential therapeutic towards clinical trials.

SPEAKER Abstracts

NEURAL CELL THERAPY FOR SPINAL CORD REPAIR

Lyandysha Zholudeva | Postdoctoral Researcher, Drexel University College of Medicine

There is a rich history of using cell transplantation to repair the injured central nervous system, but little is known about the mechanisms that contribute to repair post transplantation and how cell therapies can be used most effectively. This presentation will begin to discuss these questions by considering five key themes important to the field of cell transplantation for neural repair: Who are the cells available for use? What is being treated with cell therapy? When can treatment be applied? Where can cells be delivered? And Why should cells be used at all? With a focus on neural progenitor cells – the building blocks of the spinal cord – and pre-clinical models of spinal cord injury, how can cells be prepared or even engineered to produce effective components of the spinal cord that can repair damage? This presentation will begin by highlighting some of the early studies done in this area of research, describe how the field has changed in more recent years, and touch upon some more recent work, technological advances, and recent developments.

Team members: Michael Lane, Liang Qiang, Shelly Sakiyama-Elbert, Itzhak Fischer

Funding sources: NINDS, Wings for Life, Moseley Foundation

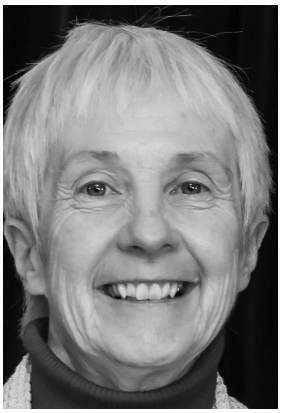
Publications:

https://www.ncbi.nlm.nih.gov/pubmed/30654638
https://www.ncbi.nlm.nih.gov/pubmed/30383302
https://www.ncbi.nlm.nih.gov/pubmed/30017476
https://www.ncbi.nlm.nih.gov/pubmed/29873284

LEADERSHIP **TEAM**

The Board & Staff of Unite 2 Fight Paralysis

BOARD OF DIRECTORS



Marilyn Smith

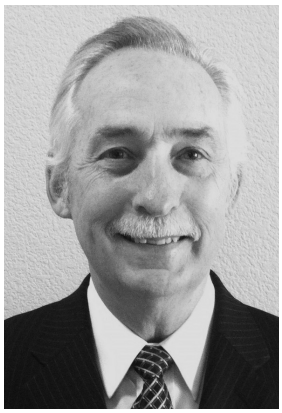
Marilyn (of Hood River, Oregon) is a graduate of the University of Michigan and brings a wide variety of skills to her work with Unite 2 Fight Paralysis. She has many years of experience as a fundraiser, event planner, and volunteer coordinator for nonprofit organizations. She has also worked as a tax consultant, webmaster, and office manager in the for-profit world. When her son was paralyzed in 2002 by a wheel that flew off of an oncoming vehicle, she immediately went to work to help him make the best of his situation. Following the "Spring Into Action" Rally in Washington, DC, in 2005, Marilyn carried her organizational skills over to U2FP, and gave thousands of volunteer hours to oversee the successful launch of the organization. She is one of the co-founders of U2FP, and served as Executive Director from 2009-2017 before moving into the role of Board President from 2017-2019. Marilyn continues to serve U2FP as a member of the Board of Directors.

Barry Munro, *Secretary*

Barry (of Toronto, Canada) is the Chief Development Officer of the Canadian Spinal Research Organization and the Ontario Neurotrauma Foundation; he also serves as director of the American Spinal Research Organization.

In 1987, Barry sustained a spinal cord injury in a diving accident, which resulted in quadriplegia. He has sat on multiple boards advocating for people with disabilities and particularly spinal cord injury research. Barry graduated from Law School in 1994 and was called to the Bar in 1996. He practiced personal injury law for over 10 years. His legal experience combined with 30 years of practical experience living with a spinal cord injury make him a formidable advocate for the disabled community. Barry has dedicated his life to assisting people living with disabilities and improving their quality of life.

Mike Burris, *President*

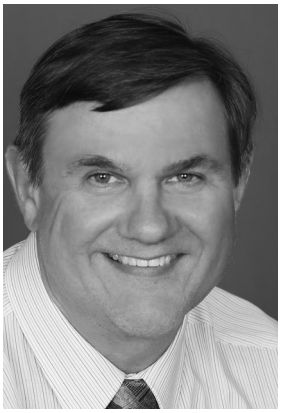


Mike (of Colorado Springs, Colorado) received his B.A. from the University of Iowa and has an M.S. in Systems Management from the University of Southern California. Mike has more than 35 years of experience in the world of space exploration. He served as an Air Force intelligence officer from 1977-1982. After he left the Air Force, he went to work at Science Applications International Corp. (SAIC) before retiring as an Assistant Vice President at the end of 2011. During his career, he worked on several space related activities such as the building of the Air Force's Consolidated Space Operations Center, the Air Force Satellite Control Network, NASA's X-43 hypersonic research vehicles, and the replacement for the Space Transportation System. Prior to joining the U2FP Board he served on three boards; he served 10-years as a school board member for the Lewis-Palmer School District #38 in Colorado during the 1990s, he was a member of the International Astronautical Congress (IAC) Space Transportation Committee from 2004-2011, and he is currently a member of Rehabilitation Institute of Chicago (RIC) Foundation Board. In July 2009 while body surfing Mike suffered a C4 incomplete SCI that, although he is ambulatory, still impacts him today. Being on the U2FP Board provides him the opportunities to advance the goals of our community and advocate for all of us to live our best possible lives. Mike was elected to the role of Board President in the spring of 2019.

Michele "Shelly" Towle

Michele (of Bismark, North Dakota) is the Assistant Director of the Spinal Cord Injury Program at DP Clinical, Inc., located in Rockville, MD. Michele has 18 years of experience in SCI clinical research. She became a study coordinator starting in 1999 when she began working with spinal cord injured patients enrolled in clinical trials. Through this early experience she came to understand the impact of a spinal cord injury, not only for individuals but also for their families and communities. Michele then moved on to monitor and manage SCI clinical trials for DP Clinical since 2003. DP Clinical is a Contract Research Organization (CRO) specializing in Spinal Cord Injury (SCI) Phase I-IV clinical programs for pharmaceutical, biotech, and medical device companies.

Over the years, Michele has seen many SCI clinical trials halted due to slow enrollment and the prohibitive cost, leaving SCI patients without a potentially beneficial new therapy. Research needs to succeed, and there remains a need for meaningful contribution to the efforts in spinal cord research. Michele advocates for better-designed protocols and validated efficacy tools to be used in clinical trials. Working with so many talented individuals with SCI expertise and a commitment to research, makes Michele ask, "how can I as a non-scientist help to advance research and clinical trials that will provide a breakthrough for spinal cord injuries?"



Alexandar "Sasha" Rabchevsky

Alexander "Sasha" Rabchevsky (of Lexington, Kentucky) is a tenured Professor of Physiology at the University of Kentucky, College of Medicine and is a core member of the Spinal Cord & Brain Injury Research Center. He is, himself, paralyzed from the chest down as the result of a motorcycle accident in 1985 which fractured his sixth thoracic vertebrae rendering him a complete T5 paraplegic. His research efforts have ensured continued extramural funding while gaining him international recognition as a leading expert in both mitochondrial dysfunction and autonomic pathophysiology following spinal cord injury, particularly the development of a hypertensive syndrome termed autonomic dysreflexia. It is the latter condition that he himself experiences on a regular basis, and his studies have advanced our understanding of how to monitor and treat such an insidious disorder. He has and continues to serve on various study sections, both federal and private, is associate editor and reviewer of various scientific journals, and his distinct studies have been funded by the National Institutes of Health, the International Spinal Research Trust, the Paralyzed Veterans Administration, the Craig H. Neilsen Foundation, the Commonwealth of Kentucky, and the University of Kentucky.

Traci Fernandez

Traci has owned and operated numerous organizations throughout her career and has held Executive positions at several Fortune 500 companies. Currently, Traci is a Founder and Managing Partner at TRYAbility in Chicago. TRYAbility provides Intensive Activity Based Rehabilitation services to individuals with Paralysis. TRYability's mission is to help patients optimize their recovery, maintain long term health and foster a connected community. Prior to TRYAbiity, Traci was a Founder and President of 3C Compassionate Care Center. As a founder of 3C, Traci successfully opened and operated two of the largest Medical Marijuana dispensaries in Illinois. Traci also was a Founder and President of Operations at iGenMedia, an application software and development company. Before opening iGen, Traci held Technical and Executive roles at Arthur Andersen, IBM and the Tribune Company. Throughout her career, Traci has excelled at both Technical and Executive positions and was twice awarded Employee of the Year for her contributions. Traci received her bachelor's degree in Information and Decision Sciences from the University of Illinois. In addition to working with U2PF, Traci founded the United Paralysis Organization after becoming paralyzed in 2008 from Transverse Myelitis. Since founding the charity, Traci has worked as an advocate, raising monies to find a cure for neurological conditions and promoting therapies for those with Spinal Cord Injuries.

Christel Mitrovitch

Christel Mitrovich is a proud San Diego native and graduate of San Diego State University where she earned her MS in Exercise Physiology. Christel is Director of Operations for Reneu Health, Inc., a Southern California team of clinical kinesiologists specializing in restorative exercise and activity-based therapies. Since beginning her career in 2002, Christel has helped to advance the field of neuro-recovery and expand the reach of post-traditional rehabilitation services through her leadership and educational development of new practitioners. Christel has worked side-by-side top researchers and practitioners in the field of SCI rehabilitation, logging several years as a Facility Director for the NeuroRecovery Network and lending her expertise to numerous research projects. Over the years, Christel has worked closely with countless patients and their families and made many friends in the SCI community. She has dedicated her career to advancing the field of neurorehabilitation, working to develop and bring new treatment options to those fighting paralysis. Christel is honored to join the Unite 2 Fight Paralysis Board of Directors and looks forward to contributing all she can to find a cure.

STAFF

Matthew Rodreick
Executive Director

Matthew (of Minneapolis, Minnesota) entered the SCI community after his son Gabe sustained a C5 injury while body surfing in Costa Rica. After leaving his position as Emergency Department Operations Supervisor for the Fairview Health System, he and Gabe traveled the world in search of the best therapeutic options, only to end up back in Minnesota advocating for cure research. Matthew led a coalition of Minnesota SCI community advocates and researchers to leverage the state legislature in pursuit of public funding for SCI research. In 2012 he made a short documentary

film featuring then Minnesota Viking punter and Twitter celebrity Chris Kluwe, spending a day in a wheelchair. The screening of "Chris Kluwe Rolls A Mile In Someone Else's Wheels" kicked off their 2013 legislative campaign. The bill was passed in 2015 as the MN SCI/TBI Research Grant Program, and Matthew is now working with advocates in Washington and Pennsylvania to pass similar legislation. He credits U2FP and Working 2 Walk with providing the knowledge, focus and energy to see the real possibility of an end to the debilitating effects of paralysis.

Sam Maddox
Scientific Advisory Board Director

Sam Maddox (of Los Angeles, California) is former Knowledge Manager and spinal cord injury research writer for the Reeve Foundation. He is the author of several books related to chronic health and paralysis, including four editions of the Paralysis Resource Guide, published by the Reeve Foundation. In 1992 Maddox wrote the first comprehensive history of spinal cord injury research, The Quest for Cure: Restoring Function After Spinal Cord Injury. He wrote and published the widely acclaimed resource book Spinal Network, and is founder of New Mobility magazine. Maddox was a panel member on The Consortium for Spinal Cord Medicine, which develops and disseminates evidence-based clinical practice guidelines to professionals and consumers. He is currently writing and producing books as a resource for the newly injured: SCI: First 90 Days. He has been a reporter for many magazines, including Time, Money and People. Maddox is a graduate of the University of Colorado, where he taught in the School of Journalism.

Mary McMenamy
Team U2FP Director (incoming)

Mary is filled with enthusiasm and a passion for the Marathon process. Having run 14 marathons herself, including the Boston Marathon, Chicago , and Twin Cities Marathon, she knows intimately the many challenges marathon training presents. Mary has a BA from the University of Minnesota in Journalism, Mass Communication and Psychology. She was in sales, branding, and marketing for 25 years. After she took a few years off to ride her BMW motorcycle around the country, she returned to college in 2011 to earn her license in Drug and Alcohol Studies and currently works with men and women transitioning from prison back to the community. An athlete all her adult life, Mary currently enjoys skiing, scuba, biking, gardening, and breaking glass to make mosaic art. Mary considers herself "differently-abled" since sustaining an SCI in 2013 and finds the curiosity and adventure are in the discovery of how to do things differently.

Kathryn Mahoney
Team U2FP Director

Kathryn (of Western Springs, Illinois) was in her senior season as a gymnast at Michigan State University when she sustained a C6 spinal cord injury from a fall during practice. She returned to MSU and graduated with a B.S. in Chemical Engineering in 2013. In 2017, she completed her M.S. in Business Analytics. An athlete her whole life, Kathryn craved physical activity and was soon introduced to adaptive sports. She has now been handcycling and playing wheelchair rugby for the last two years, and believes the mental and physical benefits of adaptive sports and the surrounding community are immeasurable. She also attends NextSteps Chicago, where the focus is on activity-based therapies. Kathryn is excited to share the mission of U2FP and facilitate the development of Team U2FP, which encourages runners and wheelchair athletes to support the search for a cure by racing in any event, from 5k's to marathons. Additionally, she motivates and assists the athletes to meet their training and fundraising goals.

Jake Beckstrom
Cure Advocacy Network Manager

Jake Beckstrom is from Watertown, Minnesota. At the age of 16, Jake had a diving accident in a backyard pool and sustained a C4-6 spinal cord injury. A lifelong love of hunting, fishing, and the outdoors led him to pursue a path of environmental sustainability. He received a B.S. in Environmental Science at Southwest Minnesota State University, and in 2015, he received a law degree and master's degree in Environmental Law and Policy at Vermont Law School. Jake is eager to use his experience in public policy and advocacy to work with the Cure Advocacy Network to lobby for smarter spinal cord injury research funding and find a cure for paralysis.

Ryan Romine
Program Manager

Ryan (of Minneapolis, Minnesota) has worked in managerial and administrative roles at mission driven organizations for the last 15 years. He has a strong background in communications, customer service, and project management. Impressed by U2FP's vision to end paralysis rather than simply accommodate it, Ryan is honored to lend his efforts in the comprehensive fight for a cure.

Kate Willette
Writer & CureCast host

Kate (of Bellevue, Washington) is a writer and activist. She holds an M.Ed and a BA in mathematics, both from the University of Washington in Seattle. When her husband broke his neck skiing in the spring of 2001, she gradually became determined to use her skills to further the cause of a cure for spinal cord injury. She published a memoir (Some Things Are Unbreakable) in 2003 that has won high praise from editors and readers alike. Her articles about the state of research science and the men and women who are engaged in it have been published in the United States, Norway, and online. In recent years she's enjoyed writing colorful, reliable, real-time narratives of U2FP events with a series of live blogs that are widely read and disseminated in the spinal cord injury community. In September of 2015 she published **Don't Call It a Miracle: The Movement to Cure Spinal Cord Injury** . This book is a must-read for advocates, a lay-friendly, beautifully illustrated summary of the scientific, regulatory, and funding problems to be solved, and what you can do to speed things along.forward.

Kelsey Peterson
Contributing Writer

Kelsey Peterson (of Minneapolis, Minnesota) received her BA in dance in 2008 from the University of Montana, and has since pursued choreography, as well as teaching dance and yoga. Since her spinal cord injury in 2012, she has been pursuing other creative endeavors. After working on the board of Get Up Stand Up to Cure Paralysis out of Minneapolis, she has embarked on her film-making journey with The Cure Map (currently in post-production). Kelsey hopes that her personal reflections on what it's like to live with a SCI will help incite action, and inspire others to join the movement to finding cures more quickly.


RECOVERY IS REFLECTED IN
NEUROPLASTICITY
VHC
LPS
LPS+TR

OUR Mission

WHO IS
UNITE 2 FIGHT PARALYSIS?

In the spring of 2005, just 6 months after the passing of Christopher Reeve, six "bionic women" organized the first Rally in Washington on behalf of the spinal cord injury community. Three of the women – Pam Bailey, Susan Maus, and Betheny Winkler – had spinal cord injuries or disease themselves. The other three – Faye Armitage, Suzanne Poon, and Marilyn Smith – all had sons with spinal cord injuries. Their collective determination to fight for a cure led to the historic Washington Rally.

Motivated by the knowledge and energy gained at the Rally, Susan, Betheny and Marilyn founded Unite 2 Fight Paralysis (U2FP) in late 2005, and a unique advocacy organization was born. In 2006 U2FP introduced the Working 2 Walk Science & Advocacy Symposium, bringing research scientists, clinicians, investors, SCI survivors and family members together for the first time. This annual conference continues to foster knowledge, collaboration and power for all of the stakeholders committed to achieving a cure for spinal cord injury.

Through the Working 2 Walk Symposium and its other outreach programs, Unite 2 Fight Paralysis has had an enormous impact in the community. We have promoted:

- Increased collaboration among research scientists;
- A committed advocacy effort that led to passage of the Christopher & Dana Reeve Paralysis Act;
- Partnerships between scientists and investors;
- Ongoing dialogues between researchers and those living with spinal cord injury;
- Individual and collective fundraising campaigns by community members to support research;
- Development of a strong core of community advocates who are empowered by their knowledge and support for each other;

Working in partnership with SCI Sucks, in 2012 U2FP created its first Scientific Advisory Board (SAB), comprised of experts in the field of neuroscience who evaluate research targeted toward repair of the chronic spinal cord injury. The SAB began work on November 1, 2012, and to date have reviewed over $9 million in targeted research funding. Their reports offer educated, reliable guidance for community members to provide financial support for research.

The Cure Advocacy Network was established in 2016 following the successful passage of the Minnesota SCI/TBI Research Grant Fund. U2FP supports, trains and leads advocates to initiate state legislative efforts to fund SCI research across the United States. We have initiated these efforts in 5 states (Minnesota, Washington, Pennslyvania, Ohio, and Wisconsin) and have secured funding in 4 so far (Minnesota, Washington, Pennsylvania, Ohio). We will have added almost $12M by the end of 2020, with 61 people with chronic injury having had an intervention.

Through the years Unite 2 Fight Paralysis has stayed true to its roots. We are governed and staffed by people who have a personal connection to paralysis; we live with it every day. We don't spend a lot of money on marketing or fundraising or salaries. We focus our time and energy on understanding the science, and bringing key players together who can advance the best therapies as quickly as possible. We are the Voice of the Cure.

Unite 2 Fight Paralysis is a 501c3 nonprofit organization, and donations are tax-deductible to the full extent of the law.

VOICE OF THE Cure A U2FP **VISION**

What is the Cure - Defining the Vision

Unite 2 Fight Paralysis uses the tagline, "Voice of the Cure". What does the word "cure" mean to us? Our vision of a cure includes:

1. Restoration of one's fully functional and healthy body, including relief from pain and spasms, return of bowel, bladder and sexual function, and recovery of normal sensation in addition to motor control. Once cured a person should be able to live independently, free of assistive devices, caregivers, catheters, etc.

2. Belief that curative therapies will come in stages, and support for advancing research into each stage as it becomes more promising.

3. Understanding that recovery will come through combinations of therapies that may vary just as much as the nature of spinal cord injuries. To this end we promote and support collaborations amongst scientists, investors, advocates, clinicians, and regulatory agencies.

4. Commitment over the long term to successive stages of recovery by helping to build the capacity necessary to optimize that recovery while refusing to be satisfied until all bodily functions are restored.

What is the Cure - Navigating the Vision

U2FP fights for a cure for the invisible ones, the severely disabled, the families who support them, and everyone who believes that it's possible, and more importantly urgent, to restore health and opportunity to these compromised lives.

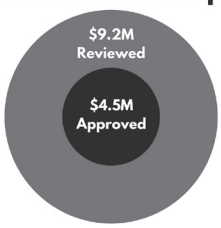
A cure does not mean that a person receives a "magic potion" injection one day and is up and running around the next. We know that after any kind of intervention to stimulate regeneration, extensive rehabilitation will be required to properly connect the motor and sensory pathways and restore function.

Let us never forget about those with complete injuries and little or no return, those who cannot use their hands or live independently, those who have no family support and are shuffled off to nursing homes, those on ventilators who require 24/7 assistance, those who do not have the time and/or money to spend the hours necessary to maximize recovery.

We don't want to start a "pity party", but we do want to increase the awareness of these realities by bringing our community into effective relationships with critical decision-makers. We believe this is the best tactic to demonstrate:

- that paralysis is a progressive and burdensome condition,
- that research science shows great promise and needs financial support,
- that restoring function will save millions of dollars for SCI survivors, their families, and society.

Research Grant Requests



*numbers as of July 2019

SCIENTIFIC ADVISORY **BOARD**

Cure research can be overwhelming and confusing. Many smaller foundations want to fund promising research, but lack the scientific expertise to vet their funding decisions. The U2FP Scientific Advisory Board is here to fill this gap. We make that expertise available to these important members of the paralysis community.

The U2FP Scientific Advisory Board (SAB) is directing dollars from SCI foundations to research that is Relevant to Chronic Injury, Replicable, Translatable and Innovative.

Relevant to Chronic Injury Giving preference to chronic injury research allows for a greater impact to the vast majority of individuals currently living with a spinal cord injury.

Replicable Research needs to be replicated in order to move toward clinical trials. We want to identify opportunities to replicate research that shows promise for innovative treatments.

Translatable Research that is applicable to the chronic injury and has the potential to move from animal models to human trials.

Innovative We wish to identify research that is asking bold questions with conservative interpretations, rather than conservative questions with bold interpretations.

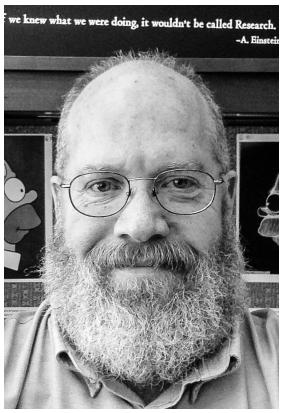
Moses V. Chao, PhD

Dr. Chao is a Professor of Cell Biology, Physiology, and Neuroscience, and professor of Psychiatry at the York University School of Medicine. He is the former President of the 42,000-member Society for Neuroscience (SFN), made up of the world's leading brain and spinal cord scientists. Dr. Chao's lab at the Skirball Institute of Biomolecular Medicine focuses on the study of molecular neurobiology and understanding the mechanisms that lead to a. the generation of neural cells and their targets, and b. the mechanisms that allow axons to project to their targets, form synapses, and signal to one another. Dr. Chao believes strongly in the necessity for more discovery science to solve the challenges of neurodegenerative disease and trauma. He brings a wealth of knowledge and experience in the field of neuroscience to our Advisory Board, and we appreciate his service.

Phillip G. Popovich, PhD, *Chair*

Dr. Popovich is the Chair and Professor in the Department of Neuroscience and Director of the Center for Brain and Spinal Cord Repair at Ohio State University. His laboratory is an interdisciplinary research group dedicated to studying the complexities of CNS injury, inflammation and tissue repair. Inflammation can have devastating consequences in the spinal cord, and the lab is striving to develop novel therapies that will manipulate or over-ride normal immune function. In addition, the Popovich lab performs replication work for the NIH. Replication is a core principle of the scientific method. To establish validity, the results of an experiment performed by one group of scientists must be evaluated by an independent group of scientists. The second group attempts to repeat the experiment of the first group, based on the original description. If the outcomes are similar, replication has been achieved and the first experiment is validated. Dr. Popovich's work in the replication process will bring a detail-oriented perspective to evaluating scientific projects.

Keith Tansey, MD, PhD



Dr. Tansey earned his BS and MS in Biology and Biomechanics from Stanford University and his MD and PhD in Neuroscience from the University of Texas Southwestern Medical Center. He then completed his Residency in Neurology at Washington University in St. Louis and then Fellowships there and at the University of California at Los Angeles in Neurorehabilitation and Spinal Cord Injury Research. He was board certified in Neurology and then subspecialty board certified in Spinal Cord Injury Medicine and Neural Repair and Rehabilitation. Dr. Tansey serves on the Board of the American Society for Neurorehabilitation and as a Board Officer for the American Spinal Injury Association and the International Society for Restorative Neurology. He is currently editing a book, "Neurological Aspects of Spinal Cord Injury" with two colleagues from Heidelberg Germany. Dr. Tansey has grants to study neural plasticity after spinal cord injury in animal models and humans from the National Institutes of Disability and Rehabilitation Research, the Department of Defense, the Veterans Administration, and the Neilsen Foundation.

Steven Kirshblum, MD

Dr. Kirshblum is nationally recognized for his work in the area of spinal cord injury rehabilitation and research. He joined Kessler Institute in 1990 and currently serves as Medical Director of the West Orange campus, as well as the Director of the Spinal Cord Injury Program. Dr. Kirshblum received his medical degree from the University of Health Sciences/Chicago Medical School and completed a residency in physical medicine and rehabilitation at Mt. Sinai Hospital in New York City, where he was a chief resident. He became board certified in 1991 and was one of the first physicians in the country to receive special certification in spinal cord injury medicine in 1998. One of the most widely respected physicians in his field, Dr. Kirshblum has delivered more than 500 lectures nationally and internationally. He is the President of the Academy of Spinal Cord Injury Professionals, Chair of the International Standards Committee for the American Spinal Association and a member of numerous advisory boards and foundations for spinal cord research.

Brian Kwon, MD, PhD, FRCSC

Dr. Kwon is the Canada Research Chair in Spinal Cord Injury and a Professor in the Department of Orthopaedics at the University of British Columbia (UBC). As a surgeon-scientist, he is particularly interested in the bi-directional process of translational research for spinal cord injury – both "bench to bedside" and "bedside back to bench". He has worked extensively on establishing biomarkers of human SCI to facilitate human trials and is leading a national biobanking effort in acute SCI. In his laboratory he has developed novel preclinical small and large animal models of SCI that can serve as the testing ground for therapeutic strategies and for conducting bedside back to bench translational studies. He has also led initiatives to establish a framework for how promising therapies for SCI should be evaluated in the laboratory setting prior to translation into human patients.

John Houle, PhD

Dr. Houle is a professor in the Department of Neurobiology & Anatomy at Drexel University College of Medicine, and director of the Spinal Cord Research Center. Prior to coming to Drexel, he taught at the University of Arkansas for Medical Sciences (UAMS), also serving as the director of the Division of Cellular and Molecular Neurobiology and the Neuroscience Research Core Facilty at UAMS. Dr. Houle has long been interested in neurotransplantation strategies to promote structural and functional recovery after spinal cord injury. Research in his laboratory is designed to examine multiple aspects of the neuronal and glial cell response to spinal cord injury, with the intent of designing a combinatorial treatment strategy for regeneration leading to functional recovery. Dr. Houle's career has been a pursuit of understanding how the regenerative response of injured neurons is regulated, why some neuron groups are strong regenerators while others exhibit very limited regenerative effort, and how we might enhance regeneration in acute and chronic injury conditions.

BACKGROUND

In September of 2012, Unite 2 Fight Paralysis - in partnership with SCI Sucks - initiated a Scientific Advisory Board. Its purpose was and is to provide investors in the SCI community with peer-reviewed recommendations on where to direct critical funding and information on specific research interests.

The SAB is made possible, in part, due to contributions from The Allergan Foundation, Cure Medical and the Hong Kong Spinal Cord Injury Foundation.

Navigating THE WORKING 2 WALK SCIENCE PRESENTATIONS

Sam Maddox

We are here at Working 2 Walk to get up to speed on the complicated science of repairing the injured spinal cord and the strategies underpinning that science. It won't take long for you to feel the weight of this material; there's no way to make it simple enough for everyone to absorb in just this setting. If you are feeling overwhelmed, you are not alone. Unless you have been steeped in all the neuroscience jargon for a while, some of these discussions about spinal cord repair strategies may leave you numb.

One of the unique beauties of Working 2 Walk is that this is not just a research science show-and-tell. It's a research science interaction. All participants are encouraged to share their stories, their work, and their goals; and to ask any question of any other participant – including the esteemed scientists. It's OK if you don't remember much high school biology, or if you have never read a neuroscience journal.

Working 2 Walk offers lay people an open forum to mix it up with the scientists, and vice versa. Scientists very much want to meet members of the SCI community and their families. It humanizes and motivates their work. So don't be shy, if you don't understand, ask! There are no dumb questions here.

You are also not alone in feeling frustration because progress seems to move so slowly. Science is hard, and it is expensive, and the leap from a promising SCI recovery study you read about in the newspaper to actual treatment is vast.

Still, we hope you gain an appreciation for the scale of the effort in labs around the world to see their research projects translate to treatments for SCI. The research community has come a long way in understanding the biology of spinal trauma, and what might be done to fix or perhaps bypass the damage. But we're not there yet.

There is no treatment queued up and waiting to be approved for either acute or chronic SCI in humans. However, there are some exciting possibilities on the horizon, including some projects now in clinical trials, and some in biotech start-up formation.

The SCI community has a role to play in keeping things moving: to remind the scientific community – with your voice and your presence – that there is urgency for treatments. This conference gives you an opportunity to tell your story and describe what matters most to you.

To help frame the discussions at the Working 2 Walk symposium, it may be helpful to reduce spinal cord injury to a general range of problems researchers are trying to solve. Let's start with the most basic question: What does an injury actually do to the cord? *(Note: We recognize the important medical value of acute SCI treatment development, however our focus is on the chronic injury.)*

The spinal cord is usually injured by a high impact event, a force that exceeds the protective armor of the backbone. Some nerve cells in the injury zone die right away, others die in the hours and days after the injury as the injury site becomes quite toxic to nerve cells. Also, trauma disrupts the basic architecture of the spinal cord. Could we perhaps **RESTORE** lost cells, or rebuild the mangled cord structure to encourage recovery?

Some spinal cord cells survive trauma but lose their axons, or long extensions akin to wiring. Research tells us these cells attempt to recover and send out axons but can't get unstuck. Could we find a way to **REGENERATE** cells and then direct the axons to reconnect?

Other cells and cell networks in the injured spinal cord are alive but disconnected from the information circuits between the brain and the cord. Can we **REJUVENATE** the spared part of the system, tapping into inherent self-repair mechanisms, or perhaps the smartness of the spinal cord itself? Can we modify other body systems, such as the immune system, to bring about better health outcomes?

At this year's Working 2 Walk we will also learn about using outside electrical signals to **RECHARGE** the body. Cleveland is the home of the most advanced functional electrical stimulation projects in the world. We will see how these engineering solutions have enabled on/off SCI recovery, and how they are being used in human trials, and even commercially.

Restoration

Cell transplantation is a potential strategy to restore function in the spinal cord, one that we all seem to get; it's easy to imagine how a new cell could replace a missing or nonworking one. Of course, it's not that "plug-and-play" easy – there is a lot to work out. Which cell, what's the right timing, what about the immune response, and what is that cell actually doing? This area of research leads us to stem cells, which includes both reasons for optimism, and for caution: because these cells are capable of growth they are also capable of too much growth.

In recent years several SCI-related cell replacement trials have been undertaken. The Miami Project, for example, has tested implants of Schwann cells (a support cell from the peripheral nervous system). Schwann cells appear to help the native cord cells but don't replace them. Several labs have tried transplanting olfactory cells, taken from the nose area. Some promising results have been published. And of course there are stem cells, already implanted in several forms in several human clinical trials for SCI, mostly for acute patients but also for injuries considered chronic.

It's too early to know what to expect regarding recovery (sample sizes are small) but in FDA-regulated trials, the cells appear to be safe (not the case in some stem cell trials outside the U.S.), and some cell therapies have had some reported benefit.

We have several researchers presenting at Working 2 Walk who will discuss stem cells:

- **Alina Garbuzov** represents the Mark Tuszynski lab at the University of California, San Diego, one of the preeminent cell therapy research facilities in the U.S. The Tuszynski group has reported functional recovery in rodent and non-human primate models of spinal cord injury, including the use of human spinal cord–derived cells into rhesus monkeys after a cervical lesion. Skilled hand function got better. They plan to see if these cells can improve function in a chronic injury model.
- **Ann M. Parr**, a Minneapolis neurosurgeon, will talk about her work implanting 3-D bioprinted scaffolds seeded with stem cells induced from patients' skin cells. She too hopes her approach will address chronic spinal cord injury, using direct custom-printed scaffolds that fit patient-specific lesion cavities.
- **Lyandysha (Lana) Zholudeva** is a post-doctoral fellow in the Michael Lane lab at Drexel University College of Medicine. (Dr. Z. will also be attending the conference.) Their work with stem cells focuses on cervical SCI and respiratory function. Dr. Z. will include an overview, from a recent journal publication, on the wide range of stem cells being investigated for spinal cord injury repair.

Regeneration

Much of what we know about spinal cord repair is pretty new. It wasn't until the 1980s that any real hopes began to emerge for restoring function. Age-old dogmas long had it that the brain and cord are a single set of wires you are born with and once damaged, can't be fixed. Not so! Scientists showed that spinal cord nerve fibers (axons) could indeed grow and reconnect again after injury – if the area near the damage is cleared of growth-blocking debris and perhaps nourished with growth additives. This remains an active area of research today; the injury environment can be made more hospitable to support survival and growth of axons.

As for the spinal neurons themselves, experiments have shown that these nerve cells are "plastic" and capable of growth, and that they might be genetically recoded to grow with an urgency they once had, when we were babies.

A major issue in regenerating spinal cord nerves is the formation of a scar-like barrier that seals off the damaged area of the spinal cord. Spinal cord nerves have a tough time trying to cross this scar. But what if the scar could be cleared away? This has become a very active research area, with a budding commercial effort, as enzyme drugs or peptides have been employed to digest or neutralize the scar; once it is neutralized, nerve cells regrow their axons and they do indeed cross the barrier. In animal experiments, significant function has been restored after application of a scar-eating drug nicknamed chase.

Again, we have several researchers presenting at Working 2 Walk who will discuss regeneration:

- **Jerry Silver** is the scientist behind NervGen Pharma, a start-up company that has high hopes to offer a therapy for SCI. Silver is well known at Working 2 Walk, having presented at several previous gatherings, always leaving behind a message of hope for treating chronic paralysis. In a nutshell, Silver found a way to kick-start regeneration by chemically modifying the scar area. He and his colleagues came up with an injectable peptide (they call it ISP -- Intracellular Sigma Peptide) that in animal testing appeared to greatly improve recovery in long-term SCI. This peptide led to the formation of NervGen, a publicly traded Canadian company. The company hopes to begin clinical trials next year. Silver is here (he's based in Cleveland at Case Western), as are Marc DePaul, who directs research at NervGen, and Ernest Wong, CEO (who is based in Colorado).

> Scientists very much want to meet the SCI community. It humanizes and motivates their work.

- **Jessica Kwok**, a neuroscientist at the University of Leeds in the U.K., focuses on the cellular structure of the spinal cord, including the "perineuronal nets" that trap spinal cord nerves and block their growth. Kwok's team has discovered a small molecule, perineuronal net inhibitor (PNNi), which in animal tests seems to untangle the nets, free up axon growth, and enhance recovery of animal hindlimb function when combined with rehabilitation. She and her team plan to apply this potential therapy to chronic SCI.

Rejuvenation

It wasn't that long ago that rehabilitation just meant learning to compensate for lost function, using devices and tools. Now we know that rehab – in the form of physical therapy and activity based training – can on its own facilitate recovery, to help the spinal cord to relearn how to initiate movement, with minimal input from the brain. Certain forms of patterned activity (e.g., stepping on a treadmill) appear to awaken dormant nerve circuits in the spinal cord, and this seems to unlock some degree of function.

Now, expanding the idea of waking up spinal circuits, researchers have added spinal cord stimulation to training and activity. In several labs in the U.S., people with SCI have been implanted with an epidural spinal cord stimulator in their back; these devices are currently on the market for treating back pain. In the SCI trials, many have seen significant voluntary recovery of function, including the ability to stand, plus benefits in cardiovascular health, bladder and even sexual function.

> Science, money and promising trial results are not enough – a treatment has to be approved, then paid for.

More human trials are on the way, including work at the Mayo Clinic in Minnesota, in Louisville, KY as part of the Reeve Big Idea (enrolling 36 patients), and in Minneapolis at the University of Minnesota.

Several stim trial researchers and participants are attending Working 2 Walk; they're happy to share their stories.

- **David Darrow** is a neurosurgeon doing the U of M trial; he is here to talk about E-STAND (Epidural Stimulation After Neurologic Damage), which is looking at the effect of epidural stimulation to restore volitional movement in 100 people with chronic complete motor spinal cord injury. Interestingly, Darrow is seeing robustly beneficial results in patients that had no intensive physical therapy before or after the implant.
- **John (Jack) Martin** is a professor at the City University of New York, School of Medicine. He is here to bridge the science, if you will, between an engineering approach and a biological one. He too uses neuromodulation techniques to waken brain and spinal cord circuits in the corticospinal tract, the spinal cord nerve pathway most important for voluntary movements. Some of these tracts are spared after trauma; Martin has shown that stimulation not only strengthens these spared connections but it also produces lasting structural changes to the corticospinal system.
- **Hunter Peckham** co-directs the MetroHealth Rehabilitation Institute here in Cleveland, and co-founded the Institute for Functional Restoration at Case Western Reserve University. He is one of the pioneers of neuroprosthetics, utilizing electrical stimulation to reactivate paralyzed muscle and to restore function lost to spinal cord injury or other paralyzing conditions. His particular specialty is upper extremity restoration.
- **Rebecca Martin** from Kennedy Krieger Institute/Johns Hopkins in Baltimore is here to talk about activity based therapies, and her work using non-invasive transcutaneous spinal cord stimulation. It is possible to stimulate the spinal cord, to "enhance excitation of spinal neural circuitry," using skin-surface stimulation. That means without any surgical implant. Skin surface stim has restored some meaningful function in people with spinal cord injuries. Cheaper, and certainly easier than surgery, but better than implants? To be determined. An implant would likely be more precisely targeted to specific circuitry. Meanwhile, non-invasive stim clinical trials are continuing in Los Angeles, Seattle, Denver, and elsewhere, and at Martin's lab in Baltimore. She recently ran an 8-week trial, combining transcutaneous spinal cord stim with intensive walking-based therapy for people with incomplete SCI, leading to better walking speed and endurance.

Rejuvenation redux/body systems

SCI does a lot more than disrupt the cord. It messes with the immune system and other organs and therefore compromises one's overall health. Here are two W2W presentations that address the effect of spinal cord injury on biological balance in the body.

- **Phillip Popovich**, who directs the Center for Brain and Spinal Cord Repair at Ohio State University, and who chairs the U2FP's Scientific Advisory Board, studies how spinal cord trauma does much more than disrupt nerve communication, it also upsets the crucial connection between the nervous and immune systems. This leads to what he calls chronic gut dysbiosis (unbalanced microbes in the intestinal tract), which can worsen the injury effect with immune dysfunction, immune suppression and "meta-inflammation." Can this be addressed? Popovich has experimented with gut biome modification, including oral probiotics.
- **Dana McTigue**, also from the Ohio State Center for Brain and Spinal Cord Repair, has looked more closely at meta-inflammation and the metabolic balance of the body. In particular, she has explored the effect of SCI on the liver, a critical organ for keeping body systems in balance. Animal data indicates that liver function is greatly affected in the short and long term after SCI, which could contribute to higher rates of insulin resistance/diabetes and elevated heart disease. McTigue ultimately hopes to find ways to combat metabolic distress.

Recharge

This is the section of the program that will showcase several methods of neuroprosthetics and neuromodulation, facilitated by **Kim Anderson-Erisman** of the Department of Physical Medicine and Rehabilitation at the MetroHealth Medical Center and Associate Director of the Institute for Functional Restoration at Case Western. Functional electrical stimulation (FES) and neuroprosthetics is a field that has long been associated with Cleveland. (See the Cleveland FES Center, fescenter.org, if you want the full history.)

Tech-wise, FES has been a hit, with a robust market for FES ergometry, and with the commercialization 20 years ago of a product to allow people with high cervical injuries to facilitate a grasp using a shoulder shrug as a trigger. Great idea, the users liked it, but the company couldn't get it properly reimbursed by insurance payers. We'll see many examples of FES here at Working 2 Walk, including systems for breathing, coughing, standing, bladder and bowel, and brain-machine interface. The question of paying for them remains challenging.

Regulatory

Science, money and promising trial results are not enough – a treatment has to be approved, and then it has to be paid for. These topics are fundamental but not always fully appreciated in a research field that has not seen many ideas run the gauntlet from lab to clinic.

- **Megan Moynahan** will facilitate the discussion around regulatory hurdles. She is the Executive Director of the Institute for Functional Restoration, a non-profit organization based at Case Western with a mission to restore function in people with spinal cord injury by building a sustainable neuromodulation business.
- **Vivek Pinto** is from the FDA. He is Assistant Director in the Division of Neuromodulation and Rehabilitation Devices in the Office of Health Technology. Any potential neuromod device will have to run through his agency.
- **Susan Miller** offers the Medicare perspective. She is a Board Certified physiatrist who is a member of the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services (CMS). If CMS won't cover it, private insurance probably won't either.

Rehab is for life

Why is it we hear about rehab techniques or products helping people but they are not widely available? Part of the problem is that rehabilitation as a field has not convincingly justified itself with cold, hard data.

Hal Hargrave started an activity based fitness center called The Perfect Step in Claremont, CA, with generous support from the Claremont Club. He and Mike Alpert, who runs the club, are big believers in "exercise is medicine." They hope to energize the healthcare industry and the fitness industry to join efforts to improve the health of people with chronic conditions, using measured results to prove that exercise works. U2FP has been helping centers like The Perfect Step to form a national association that could capture the data necessary to prove the benefit of ongoing directed exercise.

SCI 2020 panel

This is a discussion about disruption – that was the term promoted by the National Institutes of Health as it organized the SCI 2020 event earlier this year. How does the SCI community, along with those in funding, science, medicine, rehab, industry, regulation and reimbursement, move progress against the headwinds of scarcity of resources in a small marketplace? The panel members include representatives of medicine, research, industry, and the advocacy community. The panel will be asked to identify the barriers each of them face and what 'disruptions' might be necessary to remove or minimize those barriers to get to a successful outcome for all of us.

What Now?

All of this brings us to you. We believe that bringing all of us together in one room and toward one shared purpose is a necessary step toward identifying our way forward and ultimately realizing U2FP's vision: Every person has equal access to treatments that will restore health and independence after spinal cord injury.

Working 2 Walk was started in 2006 by Marilyn Smith (U2FP Board Member, and former Executive Director) and five other extraordinary women with the belief that our community needs to better understand the science in order to be effective advocates. Later, they realized that those who research the injury also need to better understand the injury through the experiences of those who live with it. That cross fertilizing continues here in this room. But it also goes out from this room to your communities, colleagues, organizations and peers.

If you need some ideas or have some ideas about how to do that, come by the U2FP table and talk to Sam Maddox (SAB Director) or Jake Beckstrom (CAN Manager) or any one of the U2FP staff or Board of Directors. If you didn't have the opportunity to do so, or want to reach out after the conference, email Matthew Rodreick at matthewrodreick@u2fp.org

Sam Maddox has been writing about spinal cord injury research for many years. His early 90s book Quest for Cure was a history of the search for treatments. Since there were none and none in the pipeline, it was mostly a narrative of hopes and promises. Today, as Director of the U2FP Science Advisory Board, Maddox sees tangible progress on many research fronts that will make a difference in the lives of people living with paralysis. Yes, we are still in the hopes and promises stage, but much, much closer to the goal.

NSCISC
NATIONAL SPINAL CORD INJURY STATISTICAL CENTER

Spinal Cord Injury Facts and Figures at a Glance

2019 SCI Data Sheet

This data sheet is a quick reference on demographics and the use of services by people with spinal cord injury in the United States (U.S.). Much of the information reflects recent data collected since 2015. Historical information reflects data collected since the early 1970s.

The National Spinal Cord Injury Database is a prospective longitudinal multicenter study that currently captures data from an estimated 6% of new SCI cases in the United States. The database has demographic and condition status data through 2018 for 33,406 people with SCI.

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Incidence

Given the current U.S. population size of 328 million people, a recent estimate showed that the annual incidence of spinal cord injury (SCI) is approximately 54 cases per one million people in the United States, or about 17,730 new SCI cases each year. New SCI cases do not include those who die at the location of the incident that caused the SCI.

- **Data Source:** Jain NB, Ayers GD, Peterson EN, et al. Traumatic spinal cord injury in the United States, 1993-2012. JAMA. 2015;313(22):2236-2243.

Prevalence

The estimated number of people with SCI living in the United States is approximately 291,000 persons, with a range from 249,000 to 363,000 persons.

- **Data Source:** Lasfargues JE, Custis D, Morrone F, Carswell J, Nguyen T. A model for estimating spinal cord injury prevalence in the United States. Paraplegia. 1995;33(2):62-68.

Age at Injury

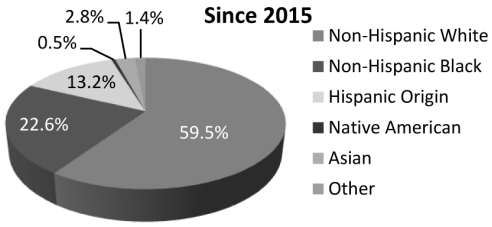
The average age at injury has increased from 29 years during the 1970s to 43 years recently.

Gender

About 78% of new SCI cases are male.

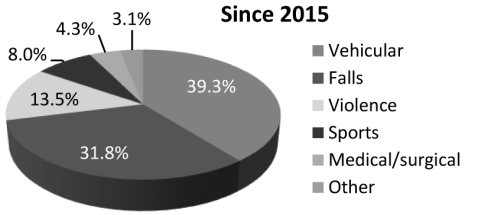
Race/Ethnicity

Recently, about 23% of injuries have occurred among non-Hispanic blacks, which is higher than the proportion of non-Hispanic blacks in the general population (13%).



Cause

Vehicle crashes are the most recent leading cause of injury, closely followed by falls. Acts of violence (primarily gunshot wounds) and sports/recreation activities are also relatively common causes.

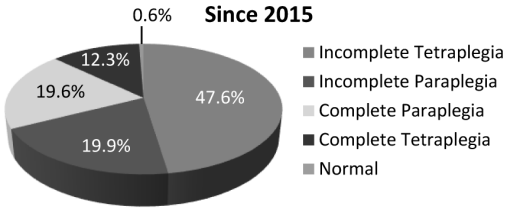


Lengths of Stay

Lengths of stay in the hospital acute care unit have declined from 24 days in the 1970s to 11 days recently. Rehabilitation lengths of stay have also declined from 98 days in the 1970s to 31 days recently.

Neurological Level and Extent of Lesion

Recently, incomplete tetraplegia is the most frequent neurological category. The frequency of incomplete and complete paraplegia is virtually the same. Less than 1% of persons experienced complete neurological recovery by the time of hospital discharge.



Spinal Cord Injury Model System
NIDILRR
National Institute on Disability, Independent Living, and Rehabilitation Research

MSKTC SCI · TBI · BURN | Model Systems Knowledge Translation Center

Education

Since 2015, about a quarter of persons with SCI have a college degree at the time of their injury, compared with 46% of people who survived 40 years of injury.

Education (%)	At Injury	Year 1	Year 10	Year 20	Year 30	Year 40
High School Only	51.7	52.7	51.3	48.2	40.5	33.9
College or Higher	24.4	26.2	26.6	24.7	35.8	46.3

Occupational Status

Since 2015, 17% of persons with SCI are employed at year 1 post-injury. The employment rate increases over time to 32% at 30 years post injury.

Status (%)	At Injury	Year 1	Year 10	Year 20	Year 30	Year 40
Employed	66.0	17.4	23.0	28.8	31.8	31.8
Student	8.1	7.5	3.1	1.0	0.3	0.0

Marital Status

Since 2015, the percentage of people who are married is relatively consistent up to year 30 post-injury, with single/never married status slowly decreasing and divorce status slowly increasing.

Status (%)	At Injury	Year 1	Year 10	Year 20	Year 30	Year 40
Single	44.9	44.0	37.6	39.4	33.9	24.6
Married	37.3	36.1	34.0	31.7	35.3	45.5
Divorced	8.6	10.9	20.1	21.0	21.7	20.2

Re-Hospitalization

Since 2015, about 30% of persons with SCI are re-hospitalized one or more times during any given year following injury. Among those re-hospitalized, the length of hospital stay averages about 19 days. Diseases of the genitourinary system are the leading cause of re-hospitalization, followed by disease of the skin. Respiratory, digestive, circulatory, and musculoskeletal diseases are also common causes.

Historical Lifetime Costs

The average yearly expenses (health care costs and living expenses) and the estimated lifetime costs that are directly attributable to SCI vary greatly based on education, neurological impairment, and pre-injury employment history. The below estimates do not include any indirect costs such as losses in wages, fringe benefits, and productivity (indirect costs averaged $76,327 per year in 2018 dollars).

	Average Yearly Expenses (in 2018 dollars)		Estimated Lifetime Costs by Age at Injury (discounted at 2%)	
Severity of Injury	First Year	Each Subsequent Year	25 years old	50 years old
High Tetraplegia (C1–C4) AIS ABC	$1,129,302	$196,107	$5,010,748	$2,753,822
Low Tetraplegia (C5–C8) AIS ABC	$816,019	$120,303	$3,661,165	$2,251,944
Paraplegia AIS ABC	$550,381	$72,909	$2,450,234	$1,608,015
Motor Functional at Any Level AIS D	$368,562	$44,766	$1,674,012	$1,181,564

Data Source: Economic Impact of SCI published in the journal *Topics in Spinal Cord Injury Rehabilitation,* Volume 16, Number 4, in 2011. ASIA Impairment Scale (AIS) is used to grade the severity of a person's neurological impairment following spinal cord injury.

Historical Life Expectancy

The average remaining years of life for persons with SCI have not improved since the 1980s and remain significantly below life expectancies of persons without SCI. Mortality rates are significantly higher during the first year after injury than during subsequent years, particularly for persons with the most severe neurological impairments.

		Life Expectancy (years) for Post-Injury by Severity of Injury and Age at Injury									
		For Persons Who Survive the First 24 Hours					For Persons Surviving at Least 1 Year Post-Injury				
Age at Injury	No SCI	AIS D—Motor Functional at Any Level	Para	Low Tetra (C5–C8)	High Tetra (C1–C4)	Ventilator Dependent Any Level	AIS D—Motor Functional at Any Level	Para	Low Tetra (C5–C8)	High Tetra (C1–C4)	Ventilator Dependent- Any Level
20	60.6	52.6	45.5	40.1	33.7	11.2	53.0	46.0	40.9	34.9	18.7
40	41.7	35.0	29.6	24.8	20.8	8.8	35.3	30.0	25.5	21.9	13.3
60	24.1	19.3	15.9	13.1	11.1	3.7	19.5	16.4	13.8	12.4	7.9

Historical Causes of Death

Persons enrolled in the National SCI Database since its inception in 1973 have now been followed for 45 years after injury. During that time, the causes of death that appear to have the greatest impact on reduced life expectancy for this population are pneumonia and septicemia. Mortality rates are declining for cancer, heart disease, stroke, arterial diseases, pulmonary embolus, urinary diseases, digestive diseases, and suicide. However, these gains are being offset by increasing mortality rates for endocrine, metabolic and nutritional diseases, accidents, nervous system diseases, musculoskeletal disorders, and mental disorders. There has been no change in the mortality rate for septicemia in the past 45 years, and there has only been a slight decrease in mortality due to respiratory diseases.

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Data from the National SCI Database is from 29 federally funded SCI Model Systems since 1973. Presently, there are 14 systems and 5 Form II (follow up) centers sponsored by NIDILRR. For a complete list of current SCI Model Systems, go to www.msktc.org/sci/model-system-centers.

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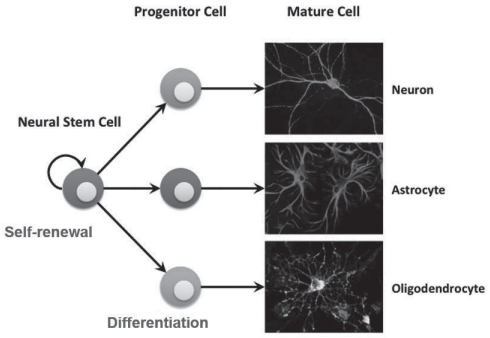
WHAT ARE STEM CELLS?

Stem cells are the foundation cells for every organ and tissue in our bodies. The highly specialized cells that make up these tissues originally came from an initial pool of stem cells formed shortly after fertilization. Throughout our lives, we continue to rely on stem cells to replace injured tissues and cells that are lost every day, such as those in our skin, hair, blood and the lining of our gut. Stem cells have two key properties: 1) the ability to **self-renew,** dividing in a way that makes copies of themselves, and 2) the ability to **differentiate**, giving rise to the mature types of cells that make up our organs and tissues.

TISSUE-SPECIFIC STEM CELLS

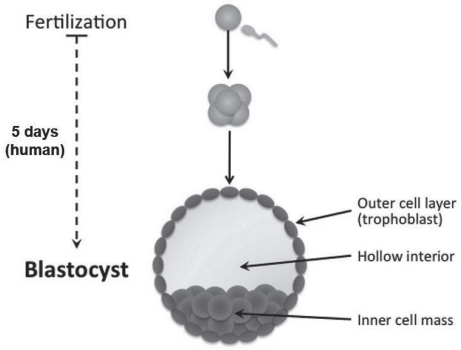
Tissue-specific stem cells, which are sometimes referred to as **"adult"** or **"somatic"** stem cells, are already somewhat specialized and can produce some or all of the mature cell types found within the particular tissue or organ in which they reside. Because of their ability to generate multiple, organ-specific, cell types, they are described as **"multipotent."** For example, stem cells found within the adult brain are capable of making neurons and two types of glial cells, astrocytes and oligodendrocytes.

Tissue-specific stem cells have been found in several organs that need to continuously replenish themselves, such as the blood, skin and gut and have even been found in other, less regenerative, organs such as the brain. These types of stem cells represent a very small population and are often buried deep within a given tissue, making them difficult to identify, isolate and grow in a laboratory setting.



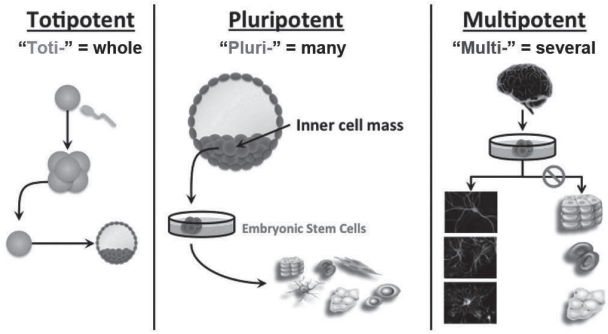
Neuron – Dr. Gerry Shaw, EnCor Biotechnology Inc.
Astrocyte – Abcam Inc.
Oligodendrocyte – Dhaunchak and Nave (2007).
Proc Natl Acad Sci USA 104:17813-8

EMBRYONIC STEM CELLS



Embryonic stem cells have been derived from a variety of species, including humans, and are described as **"pluripotent,"** meaning that they can generate all the different types of cells in the body. Embryonic stem cells can be obtained from the **blastocyst,** a very early stage of development that consists of a mostly hollow ball of approximately 150-200 cells and is barely visible to the naked eye. At this stage, there are no organs, not even blood, just an "inner cell mass" from which embryonic stem cells can be obtained. Human embryonic stem cells are derived primarily from blastocysts that were created by ***in vitro* fertilization** (IVF) for assisted reproduction but were no longer needed.

The fertilized egg and the cells that immediately arise in the first few divisions are **"totipotent."** This means that, under the right conditions, they can generate a viable embryo (including support tissues such as the placenta). Within a matter of days, however, these cells transition to become pluripotent. None of the currently studied embryonic stem **cell lines** are alone capable of generating a viable embryo (i.e., they are pluripotent, not totipotent).



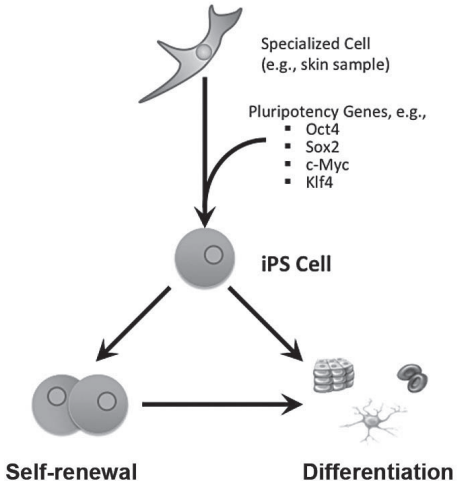
WHY ARE EMBRYONIC STEM CELLS SO VALUABLE?

Unlike tissue-specific (adult) stem cells, embryonic stem cells have the potential to generate every cell type found in the body. Just as importantly, these cells can, under the right conditions, be grown and expanded indefinitely in this unspecialized or "undifferentiated" state. These cells help researchers learn about early human developmental processes that are otherwise inaccessible, study diseases and establish strategies that could ultimately lead to therapies designed to replace or restore damaged tissues.

INDUCED PLURIPOTENT STEM CELLS

One of the hottest topics in stem cell research today is the study of induced pluripotent stem cells (iPS cells). These are adult cells (e.g., skin cells) that are engineered, or "reprogrammed," to become pluripotent, i.e., behave like an embryonic stem cell. While these iPS cells share many of the same characteristics of embryonic stem cells, including the ability to give rise to all the cell types in the body, it is important to understand that they are not identical.

The original iPS cells were produced by using viruses to insert extra copies of three to four genes known to be important in embryonic stem cells into the specialized cell. It is not yet completely understood how these three to four "reprogramming" genes are able to induce pluripotency; this question is the focus of ongoing research. In addition, recent studies have focused on alternative ways of reprogramming cells using methods that are safer for use in clinical settings.



DISEASE-OR PATIENT-SPECIFIC PLURIPOTENT STEM CELLS

One of the major advantages of iPS cells, and one of the reasons that researchers are very interested in studying them, is that they are a very good way to make pluripotent stem cell lines that are specific to a disease or even to an individual patient. Disease-specific stem cells are powerful tools for studying the cause of a particular disease and then for testing drugs or discovering other approaches to treat or cure that disease. The development of patient-specific stem cells is also very attractive for cell therapy, as these cell lines are from the patient themselves and may minimize some of the serious complications of rejection and immunosuppression that can occur following

MOVING STEM CELLS INTO THE CLINIC

Clinical translation is the process used to turn scientific knowledge into real world medical treatments. Researchers take what they have learned about how a tissue usually works and what goes wrong in a particular disease or injury and use this information to develop new ways to diagnose, stop or fix what goes wrong. Before being marketed or adopted as standard of care, most treatments are tested through clinical trials. Sometimes, in attempting new surgical techniques or where the disease or condition is rare and does not have a large enough group of people to form a clinical trial, certain treatments might be tried on one or two people, a form of testing sometimes referred to as **innovative medicine.**

For more information on how science becomes medicine, please visit **www.closerlookatstemcells.org.**

CURRENT THERAPIES

Blood stem cells are currently the most frequently used stem cells for therapy. For more than 50 years, doctors have been using bone marrow transplants to transfer blood stem cells to patients, and more advanced techniques for collecting blood stem cells are now being used to treat leukemia, lymphoma and several inherited blood disorders. Umbilical cord blood, like bone marrow, is often collected as a source of blood stem cells and in certain cases is being used as an alternative to bone marrow transplantation.

Additionally, some bone, skin and corneal diseases or injuries can be treated by grafting tissues that are derived from or maintained by stem cells. These therapies have also been shown to be safe and effective.

POTENTIAL THERAPIES

Other stem cell treatments, while promising, are still at very early experimental stages. For example, the **mesenchymal stem cell**, found throughout the body including in the bone marrow, can be directed to become bone, cartilage, fat and possibly even muscle. In certain experimental models, these cells also have some ability to modify immune functions. These abilities have created considerable interest in developing ways of using mesenchymal stem cells to treat a range of musculoskeletal abnormalities, cardiac disease and some immune abnormalities such as graft-versus-host disease following bone marrow transplant.

REMAINING CHALLENGES

Despite the successes we have seen so far, there are several major challenges that must be addressed before stem cells can be used as cell therapies to treat a wider range of diseases.

First, we need to identify an abundant source of stem cells. Identifying, isolating and growing the right kind of stem cell, particularly in the case of rare adult stem cells, are painstaking and difficult processes. Pluripotent stem cells, such as embryonic stem cells, can be grown indefinitely in the lab and have the advantage of having the potential to become any cell in the body, but these processes are again very complex and must be tightly controlled. iPS cells, while promising, are also limited by these concerns. In both cases, considerable work remains to be done to ensure that these cells can be isolated and used safely and routinely.

Second, as with organ transplants, it is very important to have a close match between the donor tissue and the recipient; the more closely the tissue matches the recipient, the lower the risk of rejection. Being able to avoid the life-long use of immunosuppressants would also be preferable. The discovery of iPS cells has opened the door to developing patient-specific pluripotent stem **cell lines** that can later be developed into a needed cell type without the problems of rejection and immunosuppression that occur from transplants from unrelated donors.

Third, a system for delivering the cells to the right part of the body must be developed. Once in the right location, the new cells must then be encouraged to integrate and function together with the body's other cells.

GLOSSARY

Blastocyst
A very early embryo that has the shape of a ball and consists of approximately 150-200 cells. It contains the inner cell mass, from which embryonic stem cells are derived, and an outer layer of cells called the trophoblast that forms the placenta.

Cell line
Cells that can be maintained and grown in a dish outside of the body.

Clinical translation
The process of using scientific knowledge to design, develop and apply new ways to diagnose, stop or fix what goes wrong in a particular disease or injury.

Differentiation
The process of development with an increase in the level of organization or complexity of a cell or tissue, accompanied by a more specialized function.

Embryo
The early developing organism; this term denotes the period of development between the fertilized egg and the fetal stage.

Embryonic stem cell
Cells derived from very early in development, usually the inner cell mass of a developing blastocyst. These cells are self-renewing (can replicate themselves) and pluripotent (can form all cell types found in the body).

Induced pluripotent stem (iPS) cell
Induced pluripotent cells (iPS cells) are stem cells that were engineered ("induced") from non-pluripotent cells to become pluripotent. In other words, a cell with a specialized function (for example, a skin cell) that has been "reprogrammed" to an unspecialized state similar to that of an embryonic stem cell.

Innovative medicine
Treatments that are performed on a small number of people and are designed to test a novel technique or treat a rare disease. These are done outside of a typical clinical trial framework.

***In vitro* fertilization**
A procedure in which an egg cell and sperm cells are brought together in a dish to fertilize the egg. The fertilized egg will start dividing and, after several divisions, forms the embryo that can be implanted into the womb of a woman and give rise to pregnancy.

Mesenchymal stem cells
Mesenchymal stem cells were originally discovered in the bone marrow, but have since been found throughout the body and can give rise to a large number of connective tissue types such as bone, cartilage and fat.

Multipotent stem cells
Stem cells that can give rise to several different types of specialized cells, but in contrast to a pluripotent stem cell, are restricted to a certain organ or tissue types. For example, blood stem cells are multipotent cells that can produce all the different cell types that make up the blood but not the cells of other organs such as the liver or brain.

Pluripotent stem cells
Stem cells that can become all the cell types that are found in an implanted embryo, fetus or developed organism. Embryonic stem cells are pluripotent stem cells.

Self-renewal
The process by which a cell divides to generate another cell that has the same potential.

Stem cells
Cells that have both the capacity to self-renew (make more stem cells by cell division) and to differentiate into mature, specialized cells.

Tissue-specific stem cells
(also known as adult or somatic stem cells)
Stem cells found in different tissues of the body that can give rise to some or all of the mature cell types found within the particular tissue or organ from which they came, i.e., blood stem cells can give rise to all the cells that make up the blood, but not the cells of organs such as the liver or brain.

Totipotent stem cells
Stem cells that, under the right conditions, are wholly capable of generating a viable embryo (including the placenta) and, for humans, exist until about four days after fertilization, prior to the blastocyst stage from which embryonic stem cells are derived.

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2013 - A grant to Dr. Susan Harkema (UofL), the first researcher to achieve paralysis recovery in humans using epidural electrical stimulation.

2014 - A grant to Courage Kenny for financial assistance to help patients access activity-based recovery therapy.

2015 - A grant to Dr. Reggie Edgerton (UCLA), the world's epidural electrical stimulation pioneer.

2016 - A grant that helped Jered Chinnock become the first patient in a Mayo Clinic study that successfully validated recovery results using epidural stimulation.

2017 - A grant that helped Jeremy Gedatus become the second Mayo Clinic study patient.

2018 - A grant for patient #3 in the Mayo Clinic study.

2019 - Now, funding patients #4, 5, & 6 at Mayo Clinic.

2020 - Next, funding an upper limb recovery project.

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Year-after-Year Working2Walk's achievements and impact continue to grow, and the Global Technology Group feels privileged to be supporting the remarkable W2W Leadership Team.

Bravo U2FP!

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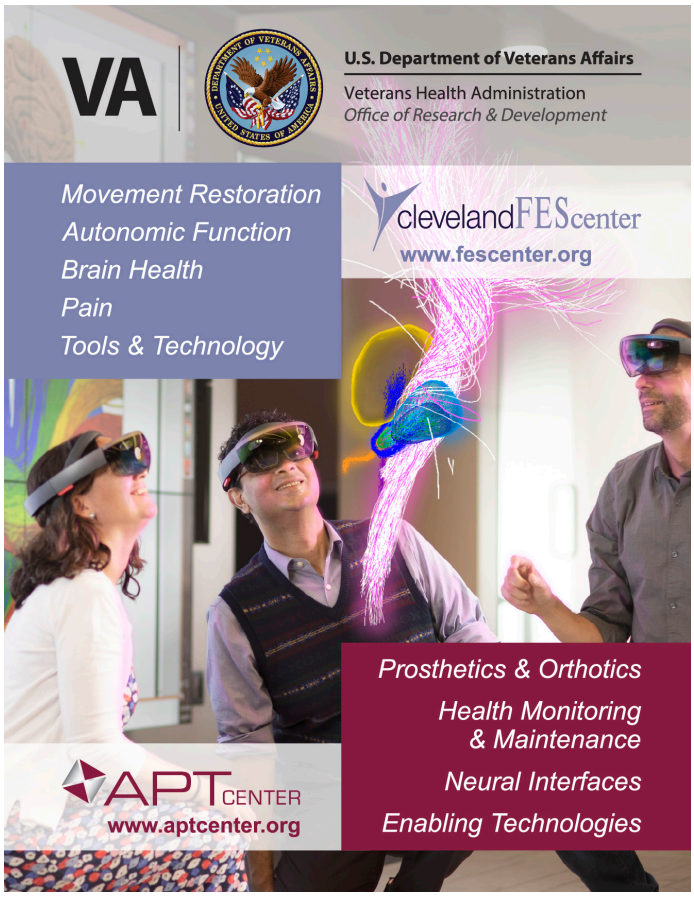

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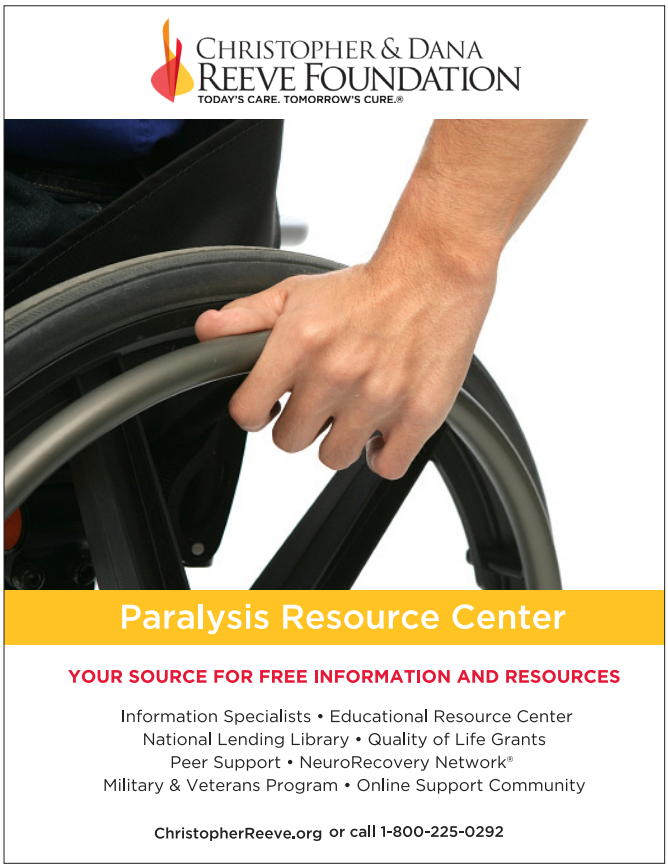
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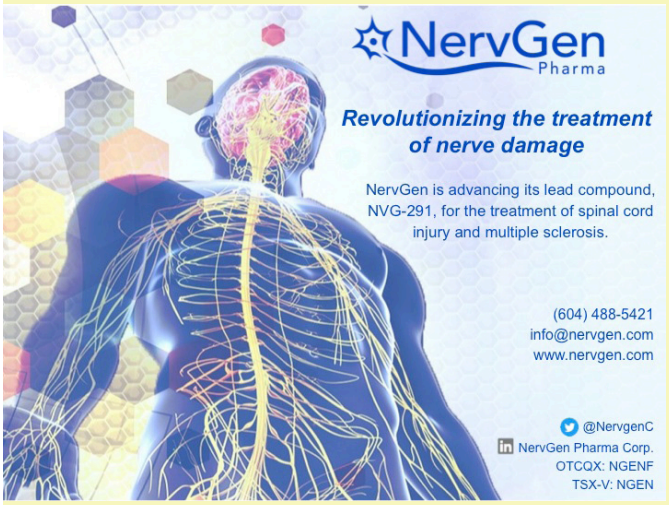
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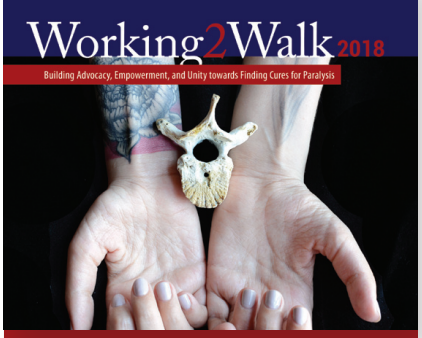
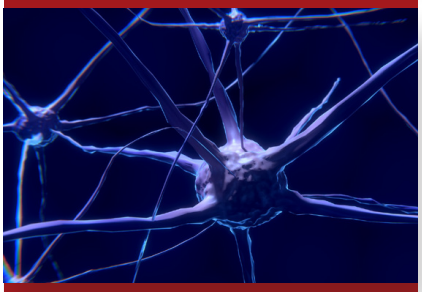


Working 2 Walk

Our conference is a collaborative gathering that prioritizes the voice of the Spinal Cord Injury (SCI) Community. We bring together research scientists, clinicians, and community advocates, along with investors and industry leaders to exchange information and strategies for achieving recovery from SCI.



Scientific Advisory Board (SAB)

Many smaller foundations want to fund promising research, but lack the scientific expertise to vet their funding decisions. The U2FP Scientific Advisory Board is here to fill this gap. Our SAB helps SCI foundations direct dollars to research that is Relevant to Chronic Injury, Replicable, Translatable and Innovative. To date, the U2FP SAB has reviewed grants totaling over $9M.

Cure Advocacy Network (CAN)

With almost $12M in legislative funding as a result of lobbying efforts by CAN Activists from within the SCI Community - the tide is turning. We're making our voices heard, and demanding to have a say in the research efforts that will affect us. We've passed Spinal Cord Injury Research Bills in Pennsylvania, Minnesota, Ohio and Washington states. We are currently working with a group of committed activists in Wisconsin where we have introduced a $10M SCI research funding Bill.

U2FP CureCast Podcast

Our podcast attempts to distill the complexities around the research economy. Our Executive Director, Matthew Rodreick and Contributing Writer, Kate Willette (author of "Don't Call It A Miracle: The Movement To Cure Spinal Cord Injury") conduct interviews with scientists, advocates and others in order to help unpack the science and deepen the dialogue with the SCI Community.

Team U2FP

Team U2FP is a way for runners and wheelers who want to participate in the movement to cure paralysis. All of our racers get free registration, a Team U2FP T-shirt, and a personal fundraising page optimized for social media sharing. Join our team in one of our featured races, or in any race in which you are participating.

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1. CONTEXT

The SCI Community must understand the broader context within which the scientific and clinical enterprise is operating. Relatedly, the Research Enterprise must understand the broader context of the lived experience with SCI so that the targets being sought match our Community's priorities

2. STRATEGY

Once we have a more realistic understanding of the context, we can then make intelligent and factually based decisions on strategic initiatives

3. VOICE

Then we can build an effective chorus of voices from amongst the community and our various stakeholders to demand the cures we seek

Working 2 Walk
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Sam Maddox, Donna Sullivan, Ryan Romine & Matthew Rodreick - Co-Chairs
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Jessica Frye - Graphic Design
John & Bogdan Biliboaca - Photographers

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