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REGENERATIVE MEDICINE 2.0

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WHAT'S NEW AT SRF?

WELCOME, TEAM!

Our friends over at Virginia Spine Institute have recently added a new member of the medical team. Dr. Colin Haines, M.D., is excited to join the "dream team" and is looking forward to working in a world-class spine care system! Specializing in the management of degenerative cervical, thoracic, and lumbar spine conditions, as well as complex spinal deformity, Dr. Haines utilizes the latest non-operative and operative treatment options, including minimally invasive and motion-preserving surgical techniques.

We are very fortunate to have found such talented, driven, and committed people to join our team over the years and to help support our mission! Continue reading to learn more about Dr. Haines!

SOCIAL MEDIA FRENZY

Have you heard? Our social media is up and running again! Be in the know by "liking" our Facebook page (Spinal Research Foundation) and subscribe to our monthly newsletter (www.spinerf.org/srf-journal-subscribe/).

CHEERS TO 10 YEARS—WE'VE GOT YOUR BACK, RESTON

It's time to clear your schedule for Sunday, October 1, 2017, as SRF and VSI host our 10th annual *We've Got Your Back* race! Come on out and join us in raising awareness about spinal injuries, disorders, and treatments! There's something for everyone at our races – from music, health fair booths, and games, to a 5k run, 1 mile fun run/walk, and tasty treats! Celebrate with and congratulate fellow Spinal Champions (those who have overcome their back or neck pain), as they cross the finish line – a perfect "cherry on top" ending to their battle with neck and back pain.

The Spinal Research Foundation is a 501(c)(3) nonprofit dedicated to improving spinal health through research, education, and patient advocacy.

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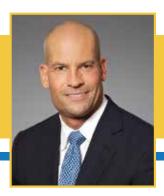


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FROM THE EDITOR: Brian R. Subach, M.D., F.A.C.S. Virginia Spine Institute



Regenerative Medicine: THE NEW FRONTIER

Regenerative medicine, or specifically regenerative medicine for spinal disorders, is a relatively new branch of spinal health care performed by physical management physicians, pain management doctors, and spinal surgeons. Many groups have a slightly different take on what regeneration means. Is it increasing the structural support or the load-bearing characteristics of the spine? Does it mean pain relief? Is it essentially a fountain of youth procedure for the joints, ligaments, tendons, and supporting structures of the spine?

The use of tissue engineering and cellular biology helps create an environment in which the regeneration of human cells may be achieved. The goal is the restoration of normal physiologic functioning, ideally devoid of pain. The earliest use of regenerative medicine dates back to 1962 when synthetic skin was used in grafting procedures for burn victims. The artificial skin provided a framework for new epithelial cells to grow and cover areas where the skin had been irreparably damaged.

Regenerative medicine for spine is developing rapidly, offering benefits to individuals suffering from pain and functional disability.

Obviously, regenerative medicine has a huge impact on the patient, but if you look at the primary cause of disability in the United States, it is a result of musculoskeletal pain following injury, disease, or illness. The chronicity of pain increases the rate of physician appointments, disability claims, and overall loss of worker productivity. Using estimates from chronic pain conditions, back pain alone counts for significant pain in nearly 100 million adults. Many of these new regenerative processes are minimally invasive and utilize regenerative medicine for the treatment of pain. Common conditions, such as spinal arthritis, may result in pain, but also injuries to cartilage, supporting tendons and muscles, bone, spinal discs, and other tissues. A successful regenerative strategy includes not only reduction of pain, but also return to activities of daily living and a greater productivity in the work place.

Now, a word about stem cells. Stem cells are undifferentiated cells taken from a mature or immature animal. These cells are capable of developing into other specialized cell types found within the body through the process called differentiation. This differentiation is triggered by the cellular environment in which the cells are placed.

There are three types of stem cells. The first is known as embryonic stem cells. These are the most immature and found within the early stages of a growing embryo, usually after it has been left to develop for a brief period of time. Harvesting from an embryo is obviously a technical challenge balancing the life of the child. More often embryonic stem cells are taken from umbilical cord blood and may be cryo-preserved for potential later use.



The second type of stem cell is an adult stem cell. These are present in all developed tissues, such as muscle, skin, and bone. These cells can self-renew and generate one specialized cell type. Generally, the tissue cells will generate cells similar to the organ in which they reside. These cells are used by the body to repair injured areas.

The third type of stem cells, which are genetically reprogrammed in the laboratory, are induced pluripotential stem cells. Essentially, these stem cells are harvested and reprogrammed in the laboratory to have a continuous supply of immature stem cells, which differentiate under the environmental factors surrounding them. This seems to avoid the ethical concerns associated with using human embryonic tissue for research and regenerative medicine strategies.

Once we discovered the ability of the body to organize and regenerate tissue after cell death, many researchers aimed their future studies at the goal of regenerative medicine and tissue engineering to replace tissue that had been damaged, lost through injury, or deteriorating with advancing age.

Many diseases and injuries that result from failing tissue could potentially be treated using regenerative medicine therapy, however, the research and the applications have both ethical and legal concerns.

As an aside, the US Food & Drug Administration (FDA) does not currently require approval of the use of adult stem cells, particularly autograft stem cells, which are stem cells that are harvested from and used by the patient. Despite this, stem cell therapy does not currently have FDA approval. Physicians prescribing these treatment modalities are using them in an "off label" application, since they believe that a treatment may benefit their patient, even though that treatment has not undergone clinical trials for the specific individual diagnosis.

In conclusion, there are a variety of regenerative therapies which may be useful in treating patients. It has been suggested that nearly 90% of the population will experience a painful condition at some time in their life that affects their ability to function on a daily basis. Some estimates associate back pain with an annual cost exceeding \$100 billion, including medical expenses and loss of productivity. Chronic pain is associated with a number of negative consequences in an individual's life, including emotional and mental distress. Chronic pain is associated with missed work, increase in sedentary choices, and a loss of productivity. Clearly this is the new frontier of spinal health care.

PRESIDENT'S NOTE: Thomas C. Schuler, M.D., F.A.C.S. Virginia Spine Institute



REGENERATIVE SPINE THERAPIES

The fountain of youth was the quest of 16th century explorer, Juan Ponce de Leon. Ponce de Leon never was able to find it, but he may have just been looking in the wrong place! Those of us in the field of spinal surgery are extremely excited about the field of regenerative medicine. Regenerative treatments may provide our patients with the ability to feel younger and function better. Regenerative medicine uses the body's own tissues to slow or reverse a degenerative process while also healing injured tissues. This area of medicine is going to become increasingly important as people not only live longer, but have expectations of higher activity levels and more fulfilling lives. As innovation allows us to live healthier and longer, something is going to need to be done to slow or reverse the degenerative process which currently plagues our bodies as we age. In the near future, it will not be uncommon for people to live over 100 years.

This is the excitement of regenerative medicine, enabling people to be treated without surgery, restore function, and regain much more active and enjoyable lives.

The two most common regenerative treatments available today are the use of platelet-rich plasma (PRP) and stem cell therapy. PRP comes from a patient's own blood, drawn from a vein, and then placed in a centrifuge. Once the blood is separated, the red blood cells and the platelet-poor plasma are discarded.

The PRP, which contains many healing factors, is then injected into the injured tissue, such as a degenerative disc, a torn ligament, or tendon, etc. We have seen great success with PRP!

Stem cell injections are another regenerative treatment in which we have also seen great success. Adult stem cells are obtained by aspirating the patient's bone marrow from the iliac crest. Once this fluid is obtained, it is placed in the centrifuge, and again, the non-essential components of the blood are discarded while the stem cells are retained for the injection. While stem cells can also be isolated from the superficial layer of fat cells and, in theory, this sounds exciting that one can have excess fat sucked out while producing a regenerative product, the reality may not be so positive. Liposuction for cosmesis is performed on the deep layer of subcutaneous fat. The stromal vascular cells, which provide fat-derived stem cells, are found in superficial, subcutaneous fat. The aspiration of fat cells from the superficial layer comes with a significant risk of unsightly skin wrinkles and poor cosmesis. In addition, the fat-derived stem cells do not seem to be as powerful in healing tissues as the bone marrow-derived stem cells.

Another common question is why embryonic stem cells are not used to stimulate healing. The answer to this is multifactorial. First, ethical debates arise



with this tissue, which concerns some, with a main concern being that embryonic stem cells are less differentiated than adult stem cells. Less differentiated stem cells have a greater risk to morph into a cancerous line than adult stem cells do. Most providers choose not to use these juvenile forms of stem cells due to the risk of an undesirable differentiation product. Lastly, most embryonic-derived stem cells die prior to or at the time of implantation, causing them to be much less potent than viable adult-derived stem cells. Furthermore, the adult-derived stem cells mentioned earlier are a direct match genetically since they come from the patient's own tissue, whereas the embryonic stem cells are from a genetically different individual.

A common question is whether to use stem cells or PRP and we have found the best solution is both! Stem cells provide the "seeds" for re-growth and PRP is the "fertilizer" to help the tissues heal and grow. When stem cells and PRP are used together, this is theoretically the equivalent of putting fertilizer around seeds to enhance their growing ability.

The use of PRP has been popularized among professional athletes with knee and other ligamentous injuries. With the addition of stem cells to these injections, the results continue to improve.

We have seen outstanding success in resolving back pain and restoring function with the application of stem cell and PRP injections to the spine; this is across a broad range of patients, from those in their twenties up to those in their seventies.

Of all of the areas that regenerative medicine is being applied, the spinal applications are demonstrating the greatest success and the best patient outcomes. In addition, when regenerative treatment is combined with quality individualized manual therapy, we are seeing exceptional results in people who had previously failed to improve with the same quality therapy without the injections.

As wonderful as our regenerative techniques are proving to be, they are pointless if we do not do what is necessary to optimize our healing. First and foremost, we need to abstain from nicotine use, as it accelerates degeneration and inhibits

healing. Patients also need to maintain proper nutrition and optimize their health condition. Other medical conditions, such as diabetes, autoimmune disorders, and vascular diseases are all detrimental to the patient's ability to experience success with regenerative treatment. Obesity, poor muscular control, poor joint mobility, and inadequate ligament flexibility are all detrimental to successful outcomes with regenerative medicine as well. The bottom line is that in order for the body to heal itself, we as patients have to do everything possible to put our bodies in the optimal state to benefit from these regenerative treatments. When the patient's condition is optimized, the results of this treatment are extremely exciting and rejuvenating.

Back to Ponce de Leon and his quest for eternal youth. The ability to heal degenerative or injured tissue is a goal that health care providers are constantly seeking. Traditionally, spinal specialists have either cut out the damaged tissue or fused an injured disc to attempt to resolve the patient's symptoms. However, healing injured discs and restoring normal function and motion is a much more desirable solution.

The entire goal of regenerative treatment is to find a better way to resolve a patient's symptoms and functional limitations without the need for an operation. This does not mean that our current surgical techniques are bad, but for select patients, a simple injection treatment with quality rehabilitation may produce an equal or superior result to surgical interventions. This is what excites us as spinal specialists. Our goal has always been to heal our patients with simple and less disruptive techniques, but that seemed to be a futuristic dream.

Our current use of PRP and stem cell regenerative therapies is revealing that the future is now.

The Spinal Research Foundation is excited to be helping clinicians advance these great innovative changes in health care. We hope to continue to find ways to improve patients' lives while minimizing the intervention required to achieving that goal. Through our research, we hope to improve patients' access to these life changing treatments by proving their success.

ASK THE EXPERT:

What is the future potential of regenerative medicine?

Center of Excellence

We are fortunate to have Research Partners across the nation that share our mission and know the importance of research programs, including regenerative therapies, which is why we asked them an important question on a hot topic that many of our patients, colleagues, and peers are asking.

Regenerative medicine, which allows the body to heal from the inside by rejuvenating cells as opposed to therapies performed from outside the body, shows promise for replacing damaged tissue and restoring function of the spine. The use of stem cells and platelet-rich plasma (PRP) are experimental, but they could prove to be an effective weapon for combating conditions of the spine caused by the aging process. Aging can compromise the integrity of cellular elements in the nucleus of the spinal discs which affects their thickness and elasticity. For some patients, employing a regenerative solution that rebuilds cells may restore the height and resilience of the discs. This could also relieve pain from pressure on spinal nerves that is caused by disc

Mark McLaughlin, M.D., F.A.C.S., F.A.A.N.S., Medical Director, Princeton Brain & Spine

degeneration or herniation.

I have been involved with research related to the texture of a spinal implant's surface and how it influences the way the body's stem cells regenerate bone for a spinal fusion. A nanoscale titanium surface causes the body to begin producing bone naturally and much more quickly than a plastic or cadaver bone. For spinal fusion patients, this means reduced inflammation, faster bone growth, and a dramatically reduced overall recovery time.

Paul Slosar, M.D., SpineCare Medical Group Regenerative medicine is a natural treatment option that bridges the gap between conservative treatments and surgery. Simply put, it's the process of creating living and functional tissues to repair or replace tissue that is lost due to age, disease, or damage. The key goal in using regenerative medicine is to aid in healing the damaged condition and to fix the root cause of the pain. Many traditional, non-operative treatments concentrate on relieving pain and other symptoms without fixing the underlying cause. For our patients that are not interested in pursuing surgical intervention, but are still looking for a solution to their pain, regenerative medicine could be the answer to rejuvenate the damaged tissue.

Virginia Spine Institute





Spi·nal Cham·pi·on (n):

/'spīnl·CHampēən/

A person who has achieved an improved quality of life through treatment for neck or back pain. The moment you step foot in our facility, our team will work collaboratively to support you in achieving the goal of becoming a "Spinal Champion". Join the "We've Got Your Back" campaign and celebrate with others by participating in our national race, featuring a 5K and a 1 mile fun run/walk!

SpineTale (n):

/spīn·tāl/

An inspirational story of a Spinal Champion, from both the patient and the clinical perspective. We love to hear from our Spinal Champions – your stories will inspire, teach, and provide hope for others who currently suffer from similar conditions. No story is too small; each journey to recovery is equally powerful and helps build awareness and hope. Celebrate your success while inspiring others and share your story!!

If you are enthusiastic about your journey to recovery and want to share your story, please contact Sabrina M. Woodlief, Associate Editor (swoodlief@spinerf.org) to learn more!



Kaitlyn Childress FROM o TO 60 (MPH)!

I started playing softball when I was eight years old and fell in love with pitching when I was 10. When I was 11 years old, I started having extreme back pain when playing softball, though. No matter what I tried, (heat, ice, rest, etc.) the pain wouldn't go away. After about two months of these symptoms, we went to my pediatrician and he said it was most likely a muscular issue. He recommended physical therapy. I went through two months of physical therapy and continued playing softball. Things seemed to get better for a short time, but the pain kept coming back. My mom took me to a chiropractor where x-rays were done. The chiropractor said that my hips were out of alignment and with a few adjustments and use of a cold laser on the area, I should be fine. We started that treatment. After approximately two months, I was pitching in a game. I was in tears after the fifth pitch. I could barely move because I was in such excruciating pain. My parents gave me Advil and Tylenol. Nothing made the pain even a little better. My mom called the chiropractor and insisted on an MRI. I had the MRI and CT scan done the next day. A few days later, I was sitting in Dr.

Good's office getting the news that I had a Bilateral Pars Defect at the L4. He told me that I would have to rest from softball and PE for three months. I could not even bend over and pick up clothes off the floor! It was the longest three months of my life! I started another round of physical therapy and after two months, I was feeling great! I could bend over and run again! I was finally able to start softball again, but always had some type of soreness in my lower back. I thought it was muscle soreness, but it would never go away. We decided to go back and see Dr. Good to be sure that the fracture wasn't worse. They did an x-ray and showed that the fracture was not healing as it should be. He gave me a few options. 1.) Rest again for another three months and then do PT again. 2.) Undergo surgery in order to repair the defect. (He strongly recommended against this option.) 3.) Perform a stem cell procedure and directly inject those cells into the fracture.

AFTER A LONG DISCUSSION WITH MY PARENTS, I OPTED TO DO THE STEM CELL PROCEDURE.



I had the procedure on June 1, 2016 at only 13 years old. It was the scariest thing that I have ever experienced, but it was so worth it! The nurses and Dr. Good helped me through it every step of the way. I recovered from the procedure after wearing a corset-style back brace for three months. During this time, I could not bend over and had to be very careful. One week after the procedure, I noticed that the pain was gone! I have not experienced pain since that time! After the three month healing milestone, I was able to do PT at home and continued doing so for two months. After my appointment with Dr. Good, I was able to increase the amount of physical exercise I could do. I started doing strength and agility training several days a week and incorporated some pitching drills. After about six weeks of only strength and agility training, I started full out pitching and fielding. I am now back to my regular routine, practicing three days a week, agility training two days a week, and tournaments on the weekends. Just after my 14th birthday, I pitched my all-time fastest at 60mph! My new goal is 65mph! I will be trying out for my middle school softball team in late March.

I have learned so much about my body and exercise throughout this entire experience. I learned to listen to my body. When there is pain, there is a reason. I have learned that stretching is so important. I now have to get to practice 30 minutes early because it takes me that long to run through my PT routine and stretch so that I feel warmed up and ready to work. I have learned that a strong core is so important for a healthy back. I can now do a three minute plank! I never thought that I would love to exercise!

If you have back pain that just does not go away, please go see Dr. Good and his team at Virginia Spine Institute! You do not need to live with the pain. Dr. Good is a friendly and honest doctor who has changed my life forever.

BECAUSE OF THIS EXPERIENCE, I AM CONSIDERING GOING INTO THE FIELD OF MEDICINE.

Perhaps one day I can help someone just as Dr. Good has helped me.

I AM NOW DOING WHAT I LOVE AND HAVE NO PAIN!!





THE CLINICAL PERSPECTIVE Christopher R. Good, M.D., F.A.C.S. Virginia Spine Institute

Kaitlyn is a very talented young athlete who suffered from spondylolysis, a very common cause of back pain in teenage athletes. The term spondylolysis applies when repetitive use causes a "stress fracture" in the area of the lumbar spine called the pars interarticularis.

The pars interarticularis is a bridge of bone that connects the strong structural bones in the front and the back of the spine together (Figures 1, 2). The "pars" is the "weak link" in this chain and can be injured, particularly in young athletes who are doing repetitive extension of the back during sports.

Spondylolysis is a very common condition affecting approximately 6% of all people. Many people have little or no symptoms and almost all teenagers do well with non-operative treatments.

We are usually able to get people back to normal fairly quickly using the appropriate exercise routine, but for a small number of patients, this either doesn't work or, as in Kaitlyn's case, doesn't last. She did everything right by resting, going to rehab, and strengthening her body, but time after time, she was simply not able to get back to normal activity.

Historically, for a patient where nothing else has worked, the next step is either to quit playing sports completely or to consider a surgical procedure to repair the fractured bone, usually using a screw-and-hook and bone graft. Given Kaitlyn's love and talent for softball, doing nothing and leaving her in pain was not a good option.

The term regenerative therapy refers to a number of exciting potential new treatments; after reviewing all the options with Kaitlyn and



Figure 1: A side view x-ray, showing the bones and discs stacked one on top of another. A stress fracture (white arrow) can be seen in the pars interarticularis, which is the bridge of bone that connects the front and the back portions of the spine together.

her family, we agreed that this would be a good treatment to try before surgery. The goal was to perform a Mesenchymal stem cell harvest, which would involve taking Kaitlyn's own stem cells from a bone in her pelvis, concentrating them, and injecting them into the area where the broken bones had never healed (Figures 3, 4).

This is a relatively new treatment and is not routinely required for patients with this condition, but given her situation, we elected to try this before moving toward a more invasive surgical procedure.

WHILE THIS IS NOT REQUIRED FOR MOST PEOPLE WITH SPONDYLOLYSIS, KAITLYN'S STORY IS A GREAT ONE TO SHOW HOW IT CAN BE USED TO HELP SOMEONE WITH A "HARD CASE".

Even after the injection, Kaitlin had to take time to rest her back and strengthen her body, but luckily after some time and a lot of hard work, Kaitlyn is back to 100% and living the life that she loves!



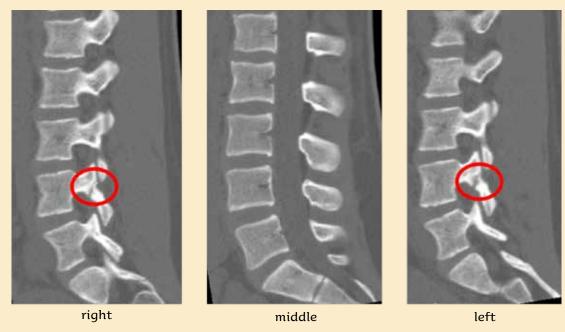


Figure 2: CT scan where the red circle indicates the stress fracture in the pars interarticularis, just present on both sides of the back.

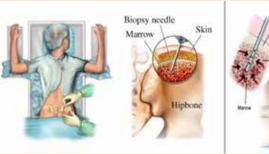




Figure 3: For a mesemchymal stem cell harvest, the patient lies on their stomach, is sedated, and is given numbing medicine to anesthetize the area. A needle is placed into the hip bone, extracting bone marrow cells found in the hip.



Figure 4: Fluoroscopy view taken on the day of the stem cell injection. Needles can be seen going into the stress fractures, injecting the concentrated stem cells that were taken from Kaitlyn's pelvic bone.

SpineTales



Dennis Dempsey THE PATH TO RECOVERY

"I'm the CAT2 Champion!", I say to myself as I'm standing on the top step, the first place spot for the VA State Off-Road Race Series CAT2 division. I look down to see a crowd of people cheering and calling my name. This time two years ago, I was questioning if I would ever even be able to ride again. What a journey!

My story begins in 2014 when my world was thrown on its heels. I'm an athlete whose body was starting to fail me. It all started when I was in my 20's. The combination of compounding and previous injuries on top of a degenerative condition of my collapsing cervical spine resulted in pressure on my neurological system.

As an athlete, I am competitive - to a fault at times. As an athlete, I am also used to "pushing through" obstacles, limitations, and even pain. Those who I have coached know my mantra:

"YOU ARE STRONGER THAN YOU THINK - DIG A LITTLE DEEPER!"

There was no "pushing through" this, though. The pain became more persistent, and as I got older, it progressed in both intensity and occurrence. "Dig a little deeper" meant that I learned to cope, but had periods where the pain would become bad enough to lay me up for a couple of days. As I got into my late 30s and 40s, it gradually started affecting more of my day-to-day activities.

I knew some degree of intervention was needed and started my research in 2013. Most of the doctors I consulted were saying "no more". No amount of training or therapy would abate the symptoms or fix things. "You're now pushing 50 and your body has taken some hard hits over the years; maybe it's time to slow down". I was being advised to stop riding, running, or doing anything that might put impact on my body. There was no doubt that I required surgery, specifically some degree of spinal fusion. But I had a very negative outlook on this type of surgery and I was dreading it. To be honest, I was outright scared of how it would affect my quality of life and impact the activities I enjoyed doing the most.



Flash forward to 2014 and my symptoms were starting to get worse. I accelerated my research, looking for top-rated doctors who specialized in the field of spine surgery, specifically for athletes. Upon meeting Dr. Brian Subach and his team at the Virginia Spine Institute, I knew I had found my solution. Dr. Subach and his team invested a significant amount of time to make sure I was properly diagnosed, educated on my situation, and that I understood my options. Most of my fears were addressed and replaced with facts and an understanding of the latest procedures available to people with issues similar to mine. I was now more comfortable with surgery and it was just a matter of when it would happen.

The matter of "when" was decided for me in July of 2014, when something triggered a massive onset of symptoms. Everything in my body was starting to shut down. I was prepared; I just never imagined the onset would be so sudden. Atrophy was setting in my arms and I was losing use of my hands. As the nerves in my cervical spine became more entrapped, the pain became constant and severe. Along with this new onslaught of pain, the right side of my body basically began to completely shut down. My arms and right leg were becoming weak and motor function was

becoming more impaired. Before I knew it, I was bed-ridden and starting to lose motor function on the entire right side of my body. Where I wasn't losing sensation, the neurological pain was unbearable. Imagine someone pouring molten lava through your body.

Everyone at VSI worked to put my surgery plan together on short-notice. The office staff even worked through issues with my uncooperative insurance carrier to get me into surgery the next day. Surgery day went smoothly and I remember waking up in recovery, noticing that all the neural pressure and pain was finally gone. I spent three days in the hospital recovering and instantly began adjusting to being pain-free. My recovery was quick and I was back on my feet in no time. Most of my recovery and pain was localized to the actual area of incision, which was manageable. I couldn't believe the improvement in my extremities. My posture had even changed and it took me a bit to get used to that.

As my recovery progressed, I noticed some lingering issues and was diagnosed with cubital tunnel. We monitored it and six months after my surgery, I was referred by Dr. Subach to another doctor to perform an ulnar nerve transposition in



my left arm, with Dr. Subach and his team advising and monitoring my recovery along the way.

Although I recovered quickly, the pain and physical impact those two surgeries had on me was intense. The steroids and pain medication wreaked havoc on my system. Within a couple of months, I dropped from a solid 180 down to 160 pounds. I was ready for all of that. What I was not ready for was the psychological and emotional impact. Unlike muscle, nerves heal slowly - frustratingly slowly. The two things I always seem to be in short supply of were needed here - patience and time.

I was feeling good and was desperate to get back in the saddle. When Dr. Subach finally cleared me for activity, I was given a "release with caution". He said, "This is going to be a long journey, so listen to your body. If it hurts, stop doing it." So, I started my therapy by hiking, then doing faster-paced walks on trails before graduating to trail running. I started back on the bike, riding smooth gravel roads before eventually making it back onto some of my favorite trails as I regained both my fitness and confidence. I noticed little things at first, areas that would normally quickly fatigue due to my c-spine issues were almost gone! I soon realized that my limits were no longer imposed on me by my broken physiology, but were now driven by muscular strength and cardiovascular endurance. My training was now both a motivation and a path to recovery. With Dr. Subach's words in mind, my mantra became "train smart, race smart, and just commit to the finish"

June 2015: I'm wearing a borrowed team jersey and straddling my bike at the starting line in the CAT2 division of a VA State series mountain bike race. It's mid-way into the Virginia Off-Road Race Series (VORS) season and while I'm definitely not new to racing, I am nervous. This is my first race after a 10-year hiatus that was brought on as a result of complications from a seriously

degenerative c-spine. It's about a minute to "gotime", but almost one year to the day after my c-spine surgery and only three months after an ulnar transposition surgery to my arm. I look down to see the homemade red compression sleeve on my left arm. It's there as both a reminder to go easy as well as to protect the incision that is still pink and healing.

On that starting line, I recognized that a lot is different for me now. I'm not 100%, but at 50 years old, I am a lot better than I was last year and even 10 years ago. Dr. Subach's words may have echoed through my head more than a few times throughout the season, especially at 4 AM during that 18-hour race when everything hurt. But what resonated the most was, "I can fix you." and

"THERE'S NO NEED TO STOP DOING WHAT YOU ENJOY, AS LONG AS YOU RECOGNIZE THE LIMITATIONS."

That first race may have been the start of a two-hour cross-country style suffer-fest, but it was a milestone in an amazing journey made possible by Dr. Subach and a great group of professionals at VSI. I finished 10th in that race and ended up taking a top 10 spot in the 2015 VA State MTB series before taking it all on again in 2016 for the win!

Yeah, "I got my life back". I feel good, maybe even a bit stronger and faster, too. I now have a yellow jersey and gold medal to prove it!







THE CLINICAL PERSPECTIVE Brian R. Subach, M.D., F.A.C.S., F.A.A.N.S. Virginia Spine Institute

I first met Dennis Dempsey in June 2014. This 48-year old consultant was extremely active, often running, biking, and weight training. He presented complaining mostly of neck pain. He had symptoms for the past 15 years, however, he had begun having symptoms involving his right arm and shoulder blade more recently. He had received a previous surgical opinion recommending a multi-level anterior cervical fusion for his complaints of decreased balance and dropping things. His two weeks of arm symptoms were not validated by an EMG study, despite the fact that he had atrophy and significant weakness in his dominant right arm.

On physical examination, he had a right-sided Spurling's sign and weakness in his finger extensors and grip. His sensation was intact. He had brisk reflexes, a positive Hoffman's sign, and positive crossed adductor sign. On an MRI scan of the cervical spine performed in May 2014, he had evidence of severe spinal stenosis at C4/5, C5/6, and C6/7. The stenosis was clearly severe enough

to flatten his spinal cord, giving him imbalance, loss of dexterity, and even caused progressive loss of strength. The arthritis and the compression of the spinal cord were clearly worse on the right side. In looking at his standing lateral x-rays, his cervical posture was clearly forward. He did not have normal lordosis. I compared the MRI scan and the standing x-rays prior to surgery (Figures 1, 2) with his ultimate surgical intervention, which was anterior cervical fusion with decompression of the spinal cord and exiting nerve roots at C4/5, C5/6, and C6/7. After surgery (Figure 3), his pain has decreased tremendously. He has normal posture and no longer is dropping things. Overall, he is much improved from his severely compromised state.

MR. DEMPSEY IS A SPINAL CHAMPION WHO EXHIBITS NOT ONLY COURAGE, BUT DEDICATION TO PHYSICAL THERAPY AND HIS OWN HEALTH.



Figure 1: Pre-operative MRI scan of the cervical spine, showing evidence of severe spinal stenosis at C4/C5, C5/C6, C6/C7.



Figure 2: Pre-operative, lateral x-ray of the cervical spine, displaying abnormal lordosis.



Figure 3: Post-operative, lateral x-ray of the cervical spine, with anterior cervical fusion.





Pat Geberth SEEK TREATMENT & FOLLOW THROUGH

My back problems started in 1998 after lifting a handicapped child while working as a physical therapist. After two discectomies, I had a fusion of L2/3 and L3/4 in 2001. All was well until summer of 2014. I was in physical therapy rehabbing my left knee from a revision of a total knee replacement. Due to a long history of left knee problems, my right leg has always been the leg I rely on. The weakness from the previous back injuries has always been in my right leg. While in therapy, the therapist noted that my right leg was getting progressively weaker and I was developing a drop foot. At the time, I had no increase in back pain. At the therapist's urging, I consulted with Dr. Subach at VSI.

The weakness and drop foot made it difficult to walk for any distance and I was more prone to falling. It was several months before I finally called for an appointment. Because I had done so well after my first fusion (2001), I did not want to acknowledge that something was wrong with my back again. After a lengthy treatment process of nerve conduction and EMG, spinal injections, decompression surgery (November 2014), continued physical therapy, and my right leg continually becoming weaker, I decided to go forward with the fusion of I 4/5 in June of 2015.

The weakness in my right leg and the drop foot has improved since surgery. I am steadier on my feet and I fall less. I am able to walk better on uneven surfaces. I am even able to get out in the field and train with my dogs. One thing I love to do is swim and snorkel. It is very difficult for me to get out of the ocean with the incline of the sand. Spring 2016, my family was able to take a trip to the Caribbean. By the end of the week, I was able to get out of the ocean without help and take short walks on the sand.

BOTH OF THESE THINGS WERE NOT POSSIBLE BEFORE MY SURGERY.

My advice to those suffering similar conditions as me: Seek treatment. Be willing to start with conservative measures first. Follow through with recommendations and therapy. I continue with an exercise program to keep my back and legs as strong as they can be. I am familiar with multiple practices through my long history of problems and as a retired physical therapist, I can honestly say that there is not one facet of VSI that doesn't go above and beyond! The care I have received from VSI, Dr. Subach, his PAs, the pain management doctors, and the entire staff has always been exemplary! Everyone is always kind, caring, and top notch!





THE CLINICAL PERSPECTIVE Brian R. Subach, M.D., F.A.C.S., F.A.A.N.S. Virginia Spine Institute

I first met Pat on September 11, 2014. This pleasant 57 year old woman presented for evaluation of a two month history of low back pain and right leg numbness. She initially had undergone previous back surgery with a lumbar discectomy at L2/3 and L3/4 in 2001, eventually culminating with a posterior lumbar instrumented fusion. After that surgical procedure, she felt great with only some mild right anterior thigh numbness until approximately two months prior to this visit. She developed right lateral thigh and calf pain with numbness.

On evaluating her x-rays and MRI scan, she appeared to have progressive degenerative changes at the L4/5 level with corresponding spinal stenosis. We initially recommended physical therapy combined with an increase in her Celebrex to twice daily. We discussed the possibility of an epidural steroid injection and attempted to avoid surgery.

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Figure 1: MRI scan showing progressive degenerative L4/5 with corresponding spinal stenosis.

She felt that physical therapy and the medications helped slightly, however, she ultimately needed the epidural steroid injection. The epidural steroid injection did nothing to alleviate the pain in her right lateral thigh and calf and she felt the numbness was progressively worsening in the past few weeks. We decided to pursue another type of epidural steroid injection as well as a nerve test on her legs to look for signs of progressive nerve damage. This second epidural steroid injection was ineffective. On strength testing, she began demonstrating weakness in right ankle dorsiflexion. The nerve test demonstrated an acute chronic L5 radiculopathy, meaning that she was demonstrating progressive nerve damage related to the spinal stenosis at L4/5 (Figure 1).

Since she had failed to improve with conservative management strategies, including the passage of time, rest, medications, physical therapy, and injection therapy, we decided to pursue surgical intervention in the form of a revision of right L4 hemilaminectomy and new right L5 hemilaminectomy for the leg pain and progressive numbness with weakness that she was experiencing. Our hope was to avoid fusion, as she had no obvious instability.

After the surgery, Patricia did extremely well. She noticed that there was near immediate resolution of the weakness in dorsiflexion, however, this was transient. After surgery in November 2014, she did well until February 2015, at which time her pain returned. Her weakness and numbness began progressively worsening and we decided to perform a revision of her previous fusion with instrumentation extending down to the L4/5 level. We removed her previous L2/3 and L3/4 hardware and put in new screws at L4/5 on both sides (Figure 2 & 3).

We were able to decompress the nerve roots nicely, reconstruct her spine with a piece of donor bone in the disc space, and place screws on both sides. By two weeks after surgery, she showed significant improvement in her low back pain with some continued mild leg numbness and weakness. Her imaging studies looked fantastic and I believe she is on the road to recovery.

Pat is a SpineTale because she has undergone a previous surgery and developed adjacent segment degeneration. Conservative management strategies failed to improve her symptoms and she underwent a minimally invasive and then a more aggressive surgical option. At this point, she has been nicely reconstructed and the pressure has been removed from her nerve roots. She is on the road to recovery.



Figure 2 & 3: X-rays of original fusion and second fusion extending down to L4/5.

SpineTales



Dylan Kiner VICTORY OVER CRIPPLING PAIN

The pain on the right side of my body started two decades ago. It wasn't just one type of pain in one specific location. I could experience sharp, stabbing pain in my neck in the morning and uncontrollable muscle spasms in my right arm later in the day. I had tingling on the right side of my face, along with facial tics and twitching. The pain often extended down into my right leg.

There was no rhyme or reason to these symptoms; they happened at random. It was a lot to deal with and I had no idea what was causing it. I worked constantly at pain management, expending a lot of energy just trying to have a normal life in spite of all the pain and spasms.

I'm a graphic designer and in order to do my work, I need to be at my computer all the time, using my right hand and arm to control a computer mouse and stylus. When the pain on the right side of my body became unbearable, it greatly affected my ability to work. I'm also a musician; I play keyboards, so not being able to use my right hand and arm made making music

nearly impossible. I have lots of DIY projects around the house that needed to be completed, but my condition kept me from doing that. Every part of my life was affected by the terrible pain and I felt very frustrated.

I consulted with several doctors in Mercer County, NJ. One neurologist found that because of my undiagnosed physical issue, I had lost strength on my right side and was losing full mobility.

After a lot of testing, the doctors narrowed it down to a problem affecting the nerves of my spine. One doctor recommended physical therapy, which helped for some time. I regained some strength and range of motion in my right arm and leg, but an unknown physical activity triggered a reversal and all of a sudden, the problem worsened and I lost all the progress I had made. I was back at square one and it was miserable.

I KEPT THINKING, "I'M A YOUNG MAN. I NEED TO FIND AN ANSWER TO THIS AND GET BACK TO HAVING A NORMAL LIFE."

I couldn't tolerate the situation much longer and had considered a future of battling the crippling pain and other symptoms for years to come, maybe for the rest of my life. That was not an acceptable option.

A few years before I reached that desperate point, I went to Dr. Mark McLaughlin, founder and Medical Director of Princeton Brain & Spine Care, for spine-related surgery and had a very positive experience. I decided to meet with Dr. McLaughlin again in hopes he could give me some answers.

After a thorough examination, Dr. McLaughlin found that I had a herniated disc in my neck that was causing the pain, numbness, and twitching on my right side. He called my symptoms cervical radiculopathy - the pain, numbness, or spasms that occur when a nerve in the cervical spine or neck becomes irritated.

For a short time, we tried to resolve the problem with conservative treatments - injections and physical therapy, but they weren't successful. At that point, Dr. McLaughlin discussed surgical options. I had always considered surgery a last resort, but because of the positive experience I had with the previous procedure that Dr. McLaughlin and his team performed, I felt comfortable going back to him for another surgery.

He explained that the well-established surgery for my condition was a fusion procedure - inserting a metal plate into the spine to stabilize the vertebrae above and below the herniated disc. Dr. McLaughlin said the procedure has been used for decades and has a high success rate, but it could restrict range of motion after surgery. Also, a concern about spinal fusion is that in some cases, immobilizing one joint in the back causes deterioration of the vertebrae above and below it because they must work harder to provide range of motion

Dr. McLaughlin also mentioned a relatively new surgical option, cervical disc arthroplasty. He said I was an ideal candidate for the procedure and it could give me a good outcome.





The procedure doesn't repair the defective disc, but rather replaces it by inserting a metal and plastic device that relieves pressure on the nerves, stopping the pain, spasms, and twitching. Dr. McLaughlin added that the device itself moves back and forth in such a way that allows the neck to move normally. I liked the idea of having normal activity opposed to the fused option. He also mentioned that a growing body of evidence shows the procedure is effective and safe.

Dr. McLaughlin explained exactly how the procedure is performed: A small incision is made in the front of the neck and the defective disc is completely removed along with any disc fragments or bone spurs pressing on the nerves. The space between the discs is raised to its normal height and the artificial disc device is inserted into the space.

After Dr. McLaughlin and his team performed the three-hour surgery, I immediately felt the difference! I had no pain anywhere on my right side. I went home within 24 hours of the procedure. Dr. McLaughlin recommended that I do eight weeks of physical therapy to completely restore flexibility and strength on my right side. He said I could return to light work within a week or two and take on a full workload in six weeks.

Along with the relief from pain, I felt a great lifting of my spirits. I looked forward to being free from the constant debilitating pain and weakness. I'm back to working full-time in my graphic design business, making music, and devoting spare time to home improvement projects and family.

AFTER MANY YEARS OF STRUGGLING WITH CRIPPLING PAIN, I HAVE A NORMAL, PRODUCTIVE LIFE AGAIN AND I'M VERY GRATEFUL.

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THE CLINICAL PERSPECTIVE Mark McLaughlin, M.D., F.A.C.S., F.A.A.N.S. Princeton Brain & Spine

Dylan first visited my office in 2012 with complaints of back pain. After a series of tests, I performed arthroplasty surgery on him that was successful - he experienced nearly complete pain relief. In a few years, however, he began to experience pain in his neck that radiated throughout his entire right side as well as muscle spasms in his back, arm, and leg. He also had tingling in his face and facial tics that occurred without warning.

When his pain became severe, Dylan visited my office again and tests revealed that a herniated disc in his neck was causing his problems. He said he had grown weary of making constant efforts to manage the pain. Understandably, Dylan was determined to find a solution and get back to enjoying a normal life with his family, his involvement with music, and his career as a graphic designer.

Conservative treatments of injections and physical therapy were unsuccessful, so I recommended cervical disc arthroplasty, a procedure that replaces a damaged disc with an artificial one. At that time, arthroplasty was considered a new procedure and most surgeons stayed with the traditional anterior cervical discectomy and fusion (ACDF), which removes the damaged disc to relieve pressure on the spinal cord or nerves and alleviate pain, then fuses two cervical vertebrae together to provide stability to the area.

Though the ACDF has a high success rate, it may lead to degeneration of surrounding vertebrae and a potentially limited range of motion in the neck post-operatively. Cervical arthroplasty, on the other hand, has a high success rate,

but a theoretically smaller chance of vertebral degeneration and a wider range of motion because the range of the joint is preserved.

For the arthroplasty, I currently use the Mobi-C Cervical Disc, an FDA-approved cobalt chromium alloy device designed to function as a cervical disc replacement for both one-level and two-level indications. The Mobi-C is comprised of two metal plates and a plastic insert that rotate and slide back and forth to allow the vertebrae above and below the device to move in a natural manner.

The procedure that I performed on Dylan was successful; he experienced complete relief of pain on his entire right side. He was pleased to return to a full work schedule and resume his other activities without pain, spasms, or facial tics.

IT WAS EXCITING FOR ME AND MY TEAM TO UTILIZE THIS INNOVATIVE CERVICAL DISC TECHNOLOGY TO PROVIDE A SOLUTION FOR DYLAN THAT IS MORE RESTORATIVE THAN OLDER TECHNIQUES THAT HAVE A SALVAGING OR PALLIATIVE INTENT.

Essentially, we gave him a new disc that is perfectly aligned in the spinal column, relieving the pain caused by his own disc impinging upon nerves and providing a wider range of motion than he would have had after a traditional ACDF procedure.

SpineTales



Bryan Newman GETTING MY LIFE BACK

The first symptoms I felt at the onset of my pain were intense lower back pain, sciatic leg pain, and foot numbness. After 18 months of these symptoms, I underwent a microdiscectomy in New York. After that surgery, I found some relief, but the symptoms quickly returned, including lower back and leg pain. Approximately two years after that initial surgery, I had an event that brought back foot numbness and chronic pain in my lower back and legs. I did two rounds of physical therapy and lost 30 pounds all in an attempt to address my problem and stop being in constant pain.

The numbness and pain shut down my life. I am an extremely active, physical person who at the time, had three children under ten years old. I was unable to do the physical activities I wanted - hiking, fishing, hunting, sports with my children, and other physical labors on our small farm. Emotionally, I was devastated. I was unsure about the future direction of my life with all these limitations imposed by my physical situation. It was a struggle to get through every day with the

pain eroding my energy, leaving little for my family after a full day as a middle school science teacher.

Two years after my microdiscectomy, the pain returned. After a very negative experience attempting to get help elsewhere, a friend recommended Dr. Subach. After meeting with Dr. Subach and his review of my situation, he recommended and supported the decision for a double fusion.

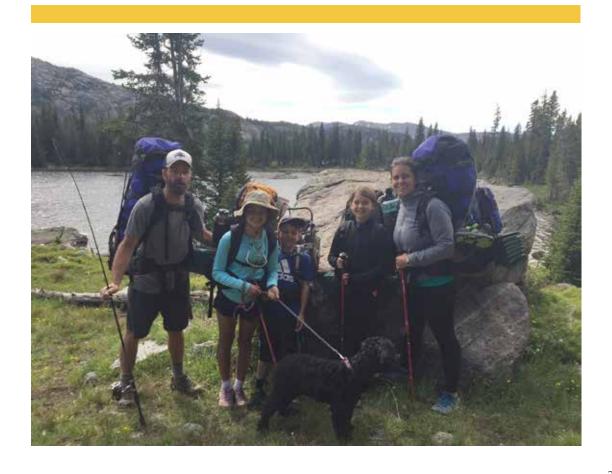
THE SURGERY NOT ONLY CHANGED MY LIFE, IT HAS GIVEN ME MY LIFE BACK.

It has allowed me to enjoy my life again and to participate in the activities that I love doing with my family. I am able to live without chronic pain. I am enjoying hiking, backpacking, traveling, coaching, fishing, hunting, working on cars, farm jobs, my children's sports, building things, and sailing – just to name a few activities that I can enjoy again. I don't like to be still and I no longer have to after the surgery.

In the spring of 2016, my daughter and I hiked the Grand Canyon, backpacking from the North Rim to the South Rim, carrying all of our supplies on our backs, and sleeping in tents under the stars. I would never have been able to do this prior to the double fusion. One of my most memorable experiences on the trip was watching the sunset at Plateau Point. I had sat there 30 years prior as a boy in my youth. I had always wanted to bring my children there, but due to the pain, never thought I would get the chance to. A few weeks after the Grand Canyon trip, my family and I went on a five night backpacking trip into the Bighorn Mountains, Cloud Peak Wilderness Area WY, elevation approximately 10,000 feet. Again, we traversed through the winding mountains and valleys with all of our gear on our backs, sleeping in our tents, and enjoying the peace. Dr. Subach's surgery on my back turned a devastating situation into one of the greatest unplanned blessings of my life.

I ADVISE OTHERS TO FIND A TEAM THAT YOU TRUST, INCLUDING YOURSELF.

For me, the surgery was the right choice, even though I was scared. I trusted Dr. Subach and know his decisions are made appropriately as to whether the surgery is the right fit for each individual person.







THE CLINICAL PERSPECTIVE Brian R. Subach, M.D., F.A.C.S., F.A.A.N.S. Virginia Spine Institute

I first met Bryan on January 2014. Mr. Newman was a 40-year old gentleman who had been dealing with years of low back pain. In 2010, he underwent a microdiscectomy at L4/5, which gave him approximately 90% relief from his leg symptoms, but really did not help his back pain. He was seen by a number of surgeons and told that he would benefit from additional surgery to stabilize and fuse the L4/5 and L5/S1 levels. Unfortunately, his surgery was denied by the insurance company at the time and he presented to see me with significant low back pain, numbness in his feet, and pain that increased with walking, radiating down the lateral thighs and into the lateral calves. He had failed rest, the passage of time, medications, and injection therapy. With his medical refractory, low back pain, and evidence of nerve damage, he was clearly a surgical candidate. We were able to obtain a new MRI scan, which demonstrated clear progression of his disease and evidence of segmental instability where the L4/5 and L5/S1 levels were wobbling from degenerative disease. He was appropriately concerned about the possibility of surgery, but was so frustrated with his low back pain and the numbness in his legs as well as his inability to walk, that he felt he had no other choice. He underwent a combined anterior and posterior surgery. He underwent anterior lumbar fusion at both L4/5 and L5/S1 levels, removing the degenerative discs and replacing them with titanium spacers and BMP (bone morphogenetic proteins).



Figure 1: MRI scan of the lumbar spine, showing evidence of degeneration and segmental instability at L4/5 and L5/S1.

Two days later, he underwent unilateral pedicle screw fixation to stabilize his spine circumferentially.

By two weeks after surgery, his right leg pain had improved dramatically. He still had some back soreness and some mild left leg pain, but was pleased with his progress.

By three months out from the operation, he was significantly better than his preoperative status. He had some mild leg pain, but felt that his back pain was down to a "4" on a visual analog scale of 10 and he had a "new lease on life". We added an anti-inflammatory agent and scheduled him for a six month post-operative visit. By four months out from surgery, he was back to work full duty and full-time. His back pain had completely resolved and his leg symptoms were barely bothersome.

Bryan is presented as a SpineTale because he had failed conservative management including rest, activity modification, physical therapy, medications, and injections. He did extremely well with a surgery that was initially denied by his insurance.

WHEN WE WERE FINALLY ABLE TO CONVINCE HIS INSURANCE COMPANY TO AUTHORIZE THE SURGERY, WE WERE ABLE TO GIVE HIM A "NEW LEASE ON LIFE".



Figure 2: Pre-operative, lateral x-ray of the lumbar spine.



Figure 3: Post-operative, lateral x-ray of the lumbar spine, with anterior lumbar fusion at L4/L5 and L5/S1, BMP disc replacement, and unilateral pedicle screw fixation.

Spinal injuries and disorders are much more common and have a greater impact than many people know. They impact people of all ages, ethnicities, and economic situations. Onset can be sudden or become chronic, growing worse each year. For these patients, each day means battling pain, crippling fatigue, muscle weakness, numbness, and more. The Spinal Research Foundation believes that these people have the right to thrive and live free from pain.

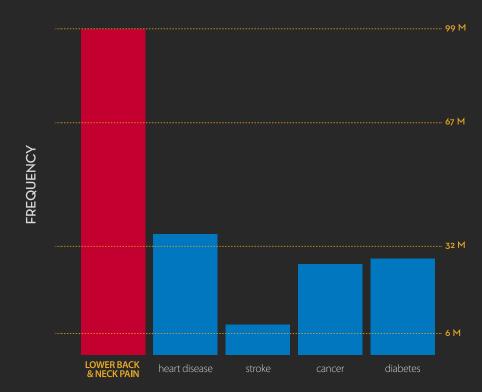
Together we will help patients return to the people and activities they love.

99.3 M

adults in the U.S. suffer from low back and neck pain each year

THE REAL IMPACT OF BACK PAIN

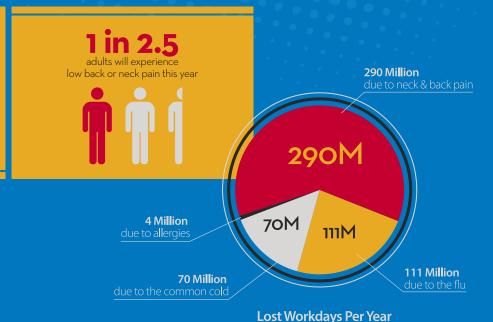








Sources: Center for Disease Control, National Academy on an Aging Society/Asthma & Allergy Foundation of America, American Diabetes Association & American Academy of Orthopedic Surgeons





Christopher R. Good, M.D., F.A.C.S. Virginia Spine Institute



Regenerative Spine Therapy: UNDERSTANDING PRP VS. STEM CELL TREATMENT

The use of regenerative therapy in the field of spinal care has been very exciting and I believe it represents a tremendous potential for breakthrough in the future.

Regenerative treatments in the spine at this point are being used to try and calm chronically irritated nerves as well as to stimulate a healing or regenerative process in multiple tissues of the spine, including many of the ligaments and muscles that protect and support the spine as well as the joints of the spine themselves.

The term "degenerative disc disease" (DDD) refers to a process that occurs in all of our discs over time. As we get older, the amount of water

content in our discs decreases. Over time, this leads to our discs, or "shock absorbers", being less hydrated, causing the discs to dry out and become more stiff as the years go by. This is a normal part of human aging, but for some people, can lead to a great deal of pain and disability. A normal disc has concentric circular outer fibers that contain the inner disc material. As degeneration occurs, the disc dries out and small cracks and tears can occur. As the degeneration continues, the disc may tear and inner material can migrate outside of the normal disc (herniation). In the end stages, bone-on-bone changes can occur with bone spurs and total loss of motion across the disc level (Figure 1).

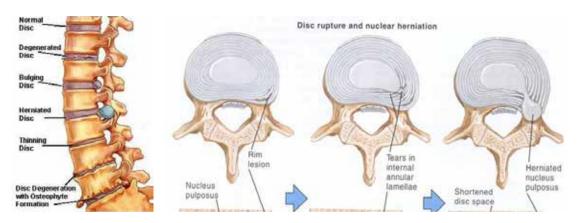


Figure 1: A side view and cross-sectional view of the lumbar spine showing a disc at varying degrees of degeneration.



Many people who develop disc disease will have symptoms such as pain, inflammation, or muscle spasms in the back. Disc disease can also lead to a more severe problem where disc material starts to encroach upon the nerves in the spinal canal, potentially causing symptoms of numbness, weakness, and tingling from spinal stenosis or disc herniation. When discs are a cause of back pain, a test called a discography is sometimes used to understand if the discs themselves are the actual cause of the pain (Figure 2).

A needle is inserted into each disc and dye is injected. In a normal disc, the dye stays in the center and fills up the disc like blowing up a balloon (red arrow). When a normal disc is injected, the patient typically does not feel any pain. In a degenerative disc, dye may flow through the cracks and tears in the disc, even leaking outside of the disc (green arrow). This may correlate with an increase in the patient's pain during the injection. In a severely degenerative disc, the dye may flow throughout the disc, filling up all the cracks and tears in the disc (blue arrow). If the injection also causes an increase in the patient's pain, the disc is confirmed to be a source of pain.

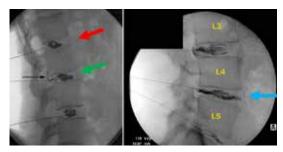


Figure 2: A side view of two lumbar spines during a lumbar discography.

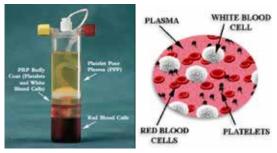


Figure 3: Platelet Rich Plasma (PRP)

The cells inside our discs do not have the ability to heal themselves. For most people, injuries to the disc can progress over the years and worsen as time goes on. I like to use the analogy of a rubber band sitting out on the desk over time. In the beginning, the disc is very elastic and flexible, but as time goes on, it may start to dry out, developing small cracks and tears.

In the end, the disc may dry up so severely that it breaks, even with a very minor stretch. The use of regenerative therapy in a disc is trying to stimulate a healing response in the disc and a decrease of inflammation in the disc, which hopefully leads to less pain in that area.

At this time, we do not have a regenerative therapy that can fully heal or regenerate a brand new disc. At present, we are seeing success in calming pain and inflammation and in some cases, showing a radiographic improvement in the structures after injection. The goal of current regenerative therapies is to improve the patient's symptoms and buy them time, trying to avoid or delay the need for a potentially more involved surgical procedure. Many different studies are ongoing at this point and great hope exists for future breakthroughs in this area. At present, available regenerative injections into the spine discs consist primarily of either plateletrich plasma (PRP) or Mesenchymal stem cells. Other substances are being investigated in various trials, but are not widely available to patients outside of research studies at this time. The exact amount or mixture of the substance that may be utilized varies depending on the patient and the structure that is trying to be addressed.

PRP is a substance taken from a patient's blood stream. To get PRP, blood is taken from a patient, just like donating blood. This blood is then prepared in a centrifuge, which spins the blood very quickly, helping to separate the blood into its separate components. PRP is the component of the blood that contains platelets as well as growth factors that are associated with tissue healing. This substance can be injected into a damaged area (muscle, ligament, disc, cartilage, etc.) to try and stimulate a healing response (Figure 3).



Figure 4: Side view x-ray (left) and MRI (middle) of a patient treated with PRP injection into the lumbar disc for low back pain. Pre-injection MRI shows degeneration at the lower two discs in the back and pain in that area was confirmed on lumbar discography. X-ray images taken during injection of PRP (right) show needles in the center of each disc, where the PRP was injected.

When we are injecting PRP into a damaged disc, we are essentially injecting a growth factor into the disc to try and stimulate the cells that are already there to have a healing response (Figure 4). When thinking about how this process may work in a disc, I like to use the analogy of a farmer planting a field. PRP is very similar to a farmer using fertilizer on top of a field. It can stimulate the seeds that are already there to grow better, but it does not put any new seeds into the area.

Stem cells are taken from a person's bone marrow or fat using a needle. Bone marrow is a combination of a number of different types of cells, some of which still have the ability to grow and differentiate (Figure 5).

When bone marrow is used, this bone marrow is then prepared in a centrifuge which helps to separate the bone marrow into its separate components. In the situation of a lumbar disc, the Mesenchymal stem cells are desired, which are concentrated and injected into the damaged area to try and stimulate a healing response (Figure 6). In this scenario, new cells are actually being injected into the area, similar to a farmer planting new seeds when they want to grow a crop.

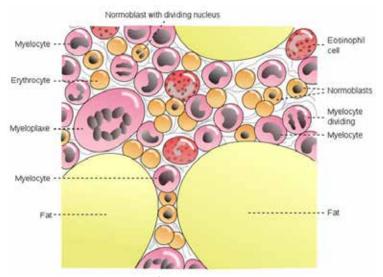


Figure 5: Composition of bone marrow

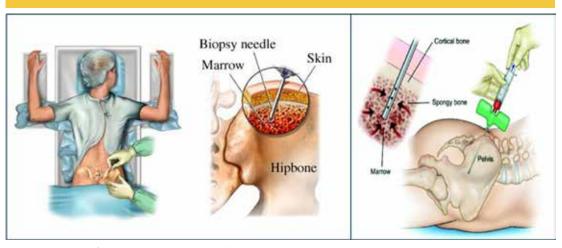


Figure 6: Injection of extracted Mesenchymal stem cells into the damaged area to stimulate a healing response

The success of any crop depends a lot on the type of environment where the crop will be sown. If a farmer has a very fertile field with great soil, plenty of sun, and a lot of water, they are more likely to grow a good crop than if they have a very dry field without fertile soil and a lack of sun and water. The same holds true for patients with disc disease. If someone is trying to get a healing response in a disc, they are more likely to get a good response with a mildly degenerated disc in a healthy patient versus a disc that has very severe degeneration in a patient who has many other medical issues (Figure 7-8).

When selecting a patient for potential regenerative therapy, it is important to consider many factors, both about the patient and about the type of degeneration that is causing their pain. A patient's age, health, and healing potential is very important to determine who may be a good candidate for regenerative therapies.

At this time, both PRP and stem cell options are being used for regenerative treatment at the level of the lumbar disc. There have been early studies and clinical experience showing promise with both, but for any given patient, a detailed evaluation needs to be undertaken in order to determine which option makes more sense.

WE NEED TO DECIDE IF PUTTING MORE FERTILIZER INTO THE AREA IS ENOUGH (PRP) OR IF WE NEED TO ACTUALLY PLANT MORE SEEDS (STEM CELLS).

In some cases, using a combination of both may be most appropriate, or perhaps, injecting different substances at different times is best, depending on the scenario. As the science and experience grows, the types of these substances that are injected and the timing will evolve. In my experience, I have been using different types of

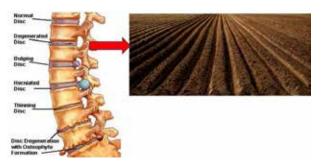


Figure 7: A mildly degenerative disc is similar to a fertile field waiting to be planted. The chances of getting a good crop to grow in this environment are high.



Figure 8: A severely degenerative disc is similar to a desert waiting to be planted. The chances of getting a good crop to grow in this environment are much lower.

regenerative therapy into the lumbar disc for over five years and I have been pleasantly surprised with how helpful it has been. I have seen a number of patients avoid low back surgery using this new and exciting technology. I first started using regenerative therapy for younger people who had more minor disc issues, but I have also seen very impressive improvements in pain for patients with more severe or complicated disc issues.

People with significant medical issues that may interfere with healing may be less likely to have a good response with a regenerative type of therapy. All of the factors about the patient, their symptoms, and what type of problem they have must be factored in when contemplating if regenerative therapy may be a good option. It would seem intuitive that a young, healthy patient with minor disc issues would have a better chance of success than an older, sicker patient with severe disc issues. The key is to match up the treatment being offered with the specific problems and values of any given patient. Only then can we determine if regenerative therapy may be helpful. As with any technology that is being developed, it is critical for the doctor to review all of the options with the patient and to help them determine if the potential benefit of the treatment is worth any associated risks.



Brandon Gwinup, Medical Assistant Virginia Spine Institute



Concentrations in the field of **REGENERATIVE MEDICINE**

Regenerative medicine can be defined as "the creation of tissues that provide, repair, replace, or restore structures and functions absent or lost due to congenital defects, ageing, disease, or damage." 1

THIS FIELD OF MEDICINE IS EXTREMELY IMPORTANT, AS LIFE ITSELF IS A DEGENERATIVE PROCESS AND LEARNING TO REVERSE DEGENERATION WILL ALLOW THOSE SUFFERING TO LEAD MORE PAINFREE LIVES.

In recent years, the concentrations within the field of regenerative medicine have expanded. Such concentrations include: tissue engineering and bio-materials, cellular therapies, medical devices, and artificial organs.

Tissue Engineering & Bio-Materials

The tissues that make up our body are specialized. For example, cardiac tissue assists in helping the heart beat and the linings of the intestines help push food through our body. To work together, these specialized cells communicate through biochemical signals. This major network of cellular communication is achieved through the

extracellular matrix (ECM). The ECM not only provides a means of communication between cells using proteins and other molecules, but assists in creating physical boundaries between tissue types. Understanding the science behind the creation of ECMs will not only help in healing damaged tissue, but will eventually play the crucial role in the creation of whole organs. The use of ECMs in tissue regeneration is an integral part of the future of regenerative medicine.²

Spinal fusion surgery involves removing the disc material between the targeted vertebrae. The vertebrae are then expanded to an appropriate height (typically restoring height to those suffering from disease) and the space between the vertebrae is filled with material to induce bone fusion. In the earlier years of spinal fusion surgery, bone graft material was an autograph, typically from the patient's hip bone. The most commonly used material now is recombinant human bone morphogenetic protein (rhBMP). rhBMP not only reduces pain and recovery time by avoiding the need for an autograph, it also has a 95% fusion rate when compared to 88% using previous methods. rhBMP is a naturally occurring protein in our bloodstream and is used by our body to stimulate bone growth and repair.3



Cellular Therapies

Every human body began from two cells (a sperm cell and an egg) and developed into a complex, cooperating biological system. This complex system was created from stem cells which differentiated into all the cells of the human body through the instruction of DNA.4 Harnessing the power of stem cells and other human cells for regenerative therapy is a promising technology. There is more than one category of stem cell. Due to media attention, most people associate stem cells as being derived from human embryos. Although stem cells from this source have the most well-rounded applications (pluripotency), these prove to not only cause ethical and moral concerns, but they are not as practical for regular use as one would think. Adult stem cells that can be derived from bone marrow are a more sensible option for use in regenerative medicine thanks to advancements in gene therapy and manipulation. This allows the adult stem cells to be "reprogrammed" into cells that can become any type of tissue they are needed for.5

When our bodies are injured, the innate immune system activates, thus inducing inflammation. This increases blood flow to the site of injury, allowing for the healing process to be expedited. However, an injury can sometimes remain even after the inflammation process. It has been found that when the inflammation process is restarted, superior healing effects can occur.⁶ This form of cellular therapy is known as prolotherapy, which can be defined as an alternative therapy for treating musculoskeletal pain that involves injecting an irritant substance (as dextrose) into a ligament or tendon to promote the growth of new tissue.⁷ Prolotherapy is typically combined with some form of physical therapy to increase effectiveness.

Another form of regenerative therapy that takes advantage of our body's own natural healing system is in the form of platelet-rich-plasma (PRP). Platelets originate from the bone marrow and travel throughout the body in the bloodstream.

Platelets will adhere to injured sites and release chemical signals that promote blood clotting, activating the healing process. PRP works by drawing blood from the intended patient and separating the platelets from the red blood cells. The resulting solution is then injected into or around the damaged tendon, disc, or muscle. The medical devices on the market used to separate the platelets from the red blood cells yield different ratios of the final product, as the optimal ratio is not yet understood.⁸⁻¹⁰

Medical Devices

While the processes behind effective healing continue to be discovered, it is sometimes necessary to use a medical device to aid with regeneration. One such device that is commonly used alongside BMP after spinal surgery is a bone growth stimulator. This device uses electrical and electromagnetic energy to aid in the formation of a solid bone fusion (arthrodesis) from either surgery or fractures. Three forms of this device are currently used: direct current stimulation (DCS), pulsed electromagnetic field stimulation (PEMFS), and capacitive coupled electrical stimulation (CCES). DCS is the only form of bone growth stimulator that must be implanted at the time of surgery. The effectiveness of these devices is based on many factors, including age, genetics, nicotine use, and bone density.11-13

Another medical device used in regenerative medicine techniques is a ventricular assist device (VAD). The purpose of this device is to assist the heart in pumping blood so that a sick heart can either heal or allow its life to be prolonged until a donor heart is found. Advancements in regenerative therapy will eventually allow cardiac stem cells to heal the diseased heart's muscles (myocardium) instead of using a donor heart. A VAD is still necessary in relieving stress on the heart while optimizing healing.¹⁴

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Artificial Organs

Organ transplants have long been a part of medical interventions. ¹⁵ The current sources of organ transplants come from either living or deceased organ donors. This system has limitations other than the sheer lack of availability of organs. With the complexity of the human immune system, rejection of donated organs is a serious issue. Advancements in the manipulation of stem cells and tissue engineering has allowed for early stages of the development of artificial organs that can be used by the host, theoretically without the risk of rejection.

Conclusion

As our knowledge in the fields of medical technology, chemistry, and biology continues to expand, the range of applications in regenerative medicine becomes greater. These applications will become more common as treatment options for the natural and induced degenerative processes of the human body. The cost, availability, and extent of these powerful technologies will continue to be the center of political and ethical debates going forward.

References

- Regenerative medicine [Internet]. The Free Dictionary.com. [cited 2017 Feb 13]. Available from: http://medical-dictionary.the free dictionary.com/regenerative+medicine
- 2. Naba A, Clauser KR, Ding H, Whittaker CA, Carr SA, Hynes RO. The extracellular matrix: Tools and insights for the "omics" era. Matrix Biology. 2016 Jan;49:10–24.
- 3. Bone Morphogenetic Protein (BMP) I Spine Surgery [Internet]. [cited 2017 Feb 14]. Available from: http://www.spinemd.com/treatments/bone-morphogenetic-protein
- 4. DSc SSP. Gray's Anatomy: The Anatomical Basis of Clinical Practice, 39e. 39 edition. Edinburgh; New York: Churchill Livingstone; 2005. 1600 p. 5. Mason C, Dunnill P. A brief definition of regenerative medicine. Regen Med. 2007 Dec 21;3(1):1–5.
- 6. Bertrand H, Reeves KD, Bennett CJ, Bicknell S, Cheng A-L. Dextrose Prolotherapy Versus Control Injections in Painful Rotator Cuff Tendinopathy. Arch Phys Med Rehabil. 2016 Jan;97(1):17–25.
- 7. Medical Definition of PROLOTHERAPY [Internet]. [cited 2017 Feb 15]. Available from: https://www.merriam-webster.com/medical/prolotherapy
- 8. Amable PR, Carias RBV, Teixeira MVT, da Cruz Pacheco Í, Corrêa do Amaral RJF, Granjeiro JM, et al. Platelet-rich plasma preparation for regenerative medicine: optimization and quantification of cytokines and growth factors. Stem Cell Res Ther. 2013;4:67.
- 9. Arnoczky SP, Delos D, Rodeo SA. What Is Platelet-Rich Plasma? Oper Tech Sports Med. 2011 Sep;19(3):142–8.
- 10. Platelets. In: The Free Dictionary.
- 11. Kaiser MG, Eck JC, Groff MW, Ghogawala Z, Watters WC, Dailey AT, et al. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 17: Bone growth stimulators as an adjunct for lumbar fusion. J Neurosurg Spine. 2014 Jul 1;21(1):133–9.
- 12. IQ Solutions I. Bone Mass Measurement: What the Numbers Mean [Internet]. [cited 2017 Feb 14]. Available from: https://www.niams.nih. gov/health_info/bone/Bone_Health/bone_mass_measure.asp 13. Hermann PC, Webler M, Bornemann R, Jansen TR, Rommelspacher Y, Sander K, et al. Influence of smoking on spinal fusion after spondylodesis surgery: A comparative clinical study. Technol Health Care. 2016 Jan 1;24(5):737–44.
- 14. Cameli M, Righini FM, Sparla S, Tacchini D, Dokollari A, Sassi CG, et al. First Evidence of Cardiac Stem Cells From the Left Ventricular Apical Tip in Patients With Left Ventricular Assist Device Implantation. Transplant Proc. 2016 Mar;48(2):395–8.
- 15. Stevens S. Synthetic Biology in Cell and Organ Transplantation. Cold Spring Harb Perspect Biol. 2016 Dec 21;a029561.



2016 WGYB RACE HIGHLIGHTS



Thank you to all who helped make our WGYB 2016 Race a success! We are so proud of our 80 Spinal Champions for reaching their goals and are thankful for the loyal support of patients, board members, sponsors, donors, and volunteers!

Even the rain didn't stop us from celebrating and having fun! (A big shout-out to BlueWater Federal Solutions who had the most company registrants and even supported through sponsorship!) Thank you, as well, to all of our sponsors: Armored Cloud, BlueWater Federal Solutions, Cameron McEvoy, K2M, Inc., Marrs & Henry Law Firm, Medtronic, Merrill Lynch, Orthofix, Potomac River Running Company, Potomac Surgical, Reston Hospital Center, Serten Advisors, The Insurance Exchange, Virginia Spine Institute, Virginia Therapy and Fitness Center, as well as in-kind support from Community Canteen, Costco, Giant, Wegmans, Whole Foods, and Zimmer Biomet.

If you're interested in learning more about our races and how you can get involved, check out the SRF website (spinerf.org) – maybe you'll see yourself in our 2016 race recap video!

The "Most Specialest" Runner

What an inspiring young man! We're not sure who is a bigger fan – us of Jacob's or Jacob of us! What we do know is that his display of kindness and generosity was a highlight to the day! Jacob, one of our youngest (and most eager) runners, along with his mom, Heather, offered the proceeds of his piggybank the day of the race. We were so touched that we asked him to come back to visit us and surprised him with a Certificate of Appreciation in recognition of his thoughtful contribution! Jacob gave us a pleasant reminder that no act is too small and when he decided to use what he's collected in his piggybank to show support for spinal health, we were truly inspired! As Jacob crossed over the finish line, he proclaimed "This is the most specialest race ever!" – and we're going to have to say the same to you, Jacob – thanks for being our "most specialest" runner! We hope to see you again at next year's race!



















Colin M. Haines, M.D. Virginia Spine Institute



WELCOME TO THE TEAM!

Why I came to VSI:

VSI is truly a national and international leader in the advancement of spine care. It is extremely rare for a spine center to have experts with the knowledge and ability to treat all problems associated with the spine in both non-operative and operative manners. Because of my respect for this approach to spinal health as well as my combined orthopedic and neurosurgical spine training, I fit naturally into VSI.

What I enjoy most about my role at VSI:

Working directly with patients to help restore functionality. Because of my position as a surgeon who typically sees and diagnoses patients first, I have the opportunity to direct patients down the proper pathway to recovery. Whether it be through physical therapy, medication adjustments, or surgery, restoring spine health has been extremely gratifying for me.

How I plan to get involved with SRF:

I have always been interested in clinical trials and will be enrolling patients into outcomes studies which have importance on both the individual and society as a whole. Specifically, I have an interest in the outcomes of motion preservation as compared to fusion surgeries and plan on continuing my research in this area through SRF.

Favorite place in the entire world:

Florence, Italy. Not only is the city and region beautiful, but the scholarly, architectural, and artistic advancements achieved here is awe-inspiring.

Two things I can't live without:

My family and exercise. Family keeps me humble, gives me purpose, and helps motivate my person-focused medical treatment style, since I aim to treat all patients like family members. Exercise allows me to decompress after a stressful day, but is also a by-product of my mentality for spine health. Maintaining physical fitness, core strength, and spine flexibility is paramount in preventing symptomatic neck or lumbar problems. By exercising, I am attempting to maximize my spine health.



Carrie Seifert, C.S.C.S. Certified Strength Coach, Virginia Spine Institute



WHAT IS YOUR "CORE"?

& How Does It Fit in With Your Regenerative Therapy

The term "core" has gained a lot of attention over the past few decades. Doctors, trainers, physical therapists, and especially the fitness world and associated media have helped propel this term to almost mythical proportions by constantly referencing it without clearly defining it. Because the core has not always been accurately described or taught in ways that make sense to the average person, it's mythical nature remains. (Even though our spine is very real and should have no comparison to mythical references.) This article is meant to explain the importance of your "core" muscles, hopefully giving more clarity to how and why it is important for everyone. Whether you are an athlete (young or old), a recovering surgical patient, or even a future surgical patient looking to prepare (or negate the need) for surgery, you should have a deep understanding and connection to your core.

If there were ever a time to truly understand how your own body works, it is when you are exploring regenerative therapies and measures. The regenerative process is only as good as the movement pattern and redevelopment process. Think of it as the crutch to the recovering broken leg. No matter how well the bone is set, if it cannot maintain its stability long enough to heal, the recovery would never be as complete.

Where is Your "Core"?

Let's start with a question. "What is your understanding of your core"? I am guessing your answer is like most of our patients...

With a shrug of doubt, you gesture towards your belly region. Or maybe you knew about the "cylinder concept", so you may have used your hands to encircle your belly, waist, and back region. Both answers would be incomplete and therefore incorrect. That region is a core (your lumber core, more specifically).

HOWEVER, WE DO NOT HAVE JUST ONE CORE, BUT RATHER THREE CORES: LUMBAR, THORACIC, AND CERVICAL.

These curves each have a group of muscles encircling them to form a "cylinder" of deep muscles that, when working properly, prevent gravity from buckling or breaking that specific curve. Unfortunately, many people with the good intention of strengthening their core unknowingly increase their odds of spinal instability, pain, and performance breakdowns over time by building imbalances within their three cores. The main point being made here is that we have three



separate curves in our spine surrounded by cylinders of muscle (core) and only by connecting those three cores (cylinders of muscle) can we hold up to the constant pressure being applied on our bodies by gravity.

Neutral spine (proper spinal posture) is dependent on an individuals' ability to engage correct postural muscles, both while at rest (sitting, lying, standing) as well as during work, play, or sport. This active support to the spine triggers an ability to release tight and tonic limb muscles from their "painfully gripping hold" that often develops when the postural support system becomes weak.

When you add each individual's personal history and the forces being placed on their bodies due to their specific activities or weaknesses, it makes sense why so many active and non-active people suffer from back pain. This can directly be connected to the fact that most people have not experienced the feeling of "Gravity Fit Posture" - the ability to feel gravity's effect on the spine lessens by engaging all three cores together. In a society where sitting has become the preferred working and resting position and where bending to pick things up happens at the belt, rather than below the pelvis, breakdown is inevitable. In order to combat this epidemic, we have to teach people how important maintaining proper posture and having an understanding of your personal movement patterns is to their regenerative therapies.

Using our Gravity Fit equipment, the first time you are instructed in the harness you will get a glimpse of how you can - and should - move again. There is no greater feeling than helping a patient that has been dealing with years of pain throughout everyday movements (both before and after surgery) feel how to activate and connect their cores, relieving them of their pain. Giving them the tools to sit and stand with greater ease and significantly less pain is amazing. However, that is also when the ultimate challenge begins because learning to change your posture is not easy to do. Sustaining it is a much more difficult task. Pain can be a great motivator as well as a valuable educator. Anyone dealing with pain on a daily basis is much more likely to know whether they are getting beginning movement patterns right or wrong while training with a qualified movement specialist. If a movement hurts, it's wrong. If you can activate

things correctly and the pain decreases significantly or goes away completely, then you are much more likely to pay attention and get it right more often in the future. While it may not be training for the Superbowl, a marathon, or the Olympics,

TRAINING YOUR BODY TO MOVE IN PAIN-FREE PATTERNS WHILE TRAINING TO DO THE HARDEST THING YOU DO WELL IS THE KEY TO LIFE.

By increasing postural confidence and knowing which movements are pain-free, you can progressively work towards more functional ranges, leading us to more sustainable recovery improvements.

Changing Posture through Exercise

Posture needs to be conscious, consistent, and deliberate, especially when first learning to activate it. It is not the age of the "suck it in, shoulders back, chin up" mantra that seems to have been ingrained into our genetic makeup. It is something that should be instructed by a professional and implemented gradually into daily activities to ensure positive results. If you find yourself questioning your own posture and/or balance or are experiencing pain while exercising, come into VTFC for a posture evaluation. For those who are in the Reston area, we offer low level Pilates and Gravity Fit classes for those looking to maintain and strengthen their own Gravity Fit Posture. These classes are a great way to practice with cues and guidance under the watchful eye of myself and other professionals. However, we ask that before you jump into one of our Pilates classes, you schedule a personal evaluation with one of our trainers (myself included!). This will give us the opportunity to assess your specific needs while giving you a chance to go over a few of the basic exercises to make your first time as seamless to you and the class as it can be. By developing stronger muscles, you will be less likely to reinjure or strain your back muscles. After investing so much into receiving regenerative therapies, why put yourself back at risk? Continue your journey of strengthening your core. We'll be right beside you every step of the way.

Colin Haines, M.D.Virginia Spine Institute



DISCOGENIC PAIN & REGENERATIVE TREATMENTS

Back pain is an extremely common cause of disability with a monthly prevalence of 39% and lifetime prevalence of 80%¹⁻². This has huge financial implications to society, costing an estimated \$100 billion every year³. Despite its frequency, the underlying cause of back pain often times is undiagnosed because there are many potential causes of low back pain, including the muscles, bones, joints, nerves, and discs in the lumbar spine.

Back pain that originates from the disc, so called discogenic pain, can be challenging to diagnose. Disc degeneration seen on MRI is frequently asymptomatic, leading to many physicians ignoring the disc as a major pain generator⁴. However, major research has shown that back pain frequently is the source of both acute and chronic pain.

The intervertebral discs consist of two major components: an inner, gelatinous nucleus pulposus and the outer strength layer, the annulus fibrosus (Figure 1). The nucleus pulposus predominately functions as the shock absorber, dispersing force from one vertebral body to the next. It has a high water content which assists in the relatively equal force transmission. The annulus is the surrounding layer that contains the nucleus. The disc itself requires nutrition, but does not have a strong, direct supply. There are small blood vessels that minimally penetrate the outer layers of the annulus, but none that dive deep into the inner structure of the disc (Figure 2). The adjacent vertebral bodies, which have a robust vascular supply, provide the majority of nutrient delivery via diffusion through the endplates. Unfortunately, this property makes repair of damage to both the nucleus and annulus very challenging.

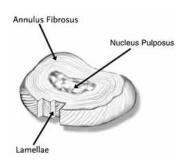


Figure 1: Disc Anatomy (Medtronic. Basic Anatomy & Pathology of the Spine)

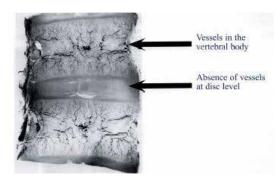


Figure 2: Lateral view showing vessels of the vertebral bodies. (Medtronic. Basic Anatomy & Pathology of the Spine)



The disc has multiple nerves that supply sensory innervations⁵. Anteriorly, the sympathetic plexus provides the vast majority of sensation. Posteriorly, the sinuvertebral nerve is the major sensory component with smaller contributions from the grey rami communicans. Laterally, the grey rami communicans is the most important neural contributor. Furthermore, the vertebral endplates experience abnormal force as the discs become incompetent. This can result in endplate damage which can lead to pain transmitted by both sympathetic plexus and bone marrow nerves. Regardless of the specific nerve involvement, it is clear that there is sensory involvement of the intervertebral discs from an anatomic perspective.

Diagnosis of disc degeneration as the specific cause of back pain can also be challenging. Clinically, pain is located most commonly in the middle of the low back. There may be pain laterally in the paraspinal musculature, but that is usually due to dynamic compensation to the disc derangement. Pain is often present with bony palpation, as that transmits translational force through the incompetent disc. Flexion classically worsens symptoms since the highest forces are placed on the disc in that position, but extension may also elicit discomfort. The centralization phenomenon, first described by McKenzie, is commonly seen with discogenic pain⁶. This occurs when diffused back and extremity pain concentrates in the lumbar spine with repetitive flexion and extension. The bony vibration test is another specific examination technique that may assist in discogenic pain diagnosis. To perform this, an instrument that causes mechanical vibration is placed directly onto the spinous process of interest⁷. Pain reproduction supports the diagnosis of discogenic pain.

Imaging assessment of discogenic symptomatology is paramount in diagnosis. Routine radiographs frequently demonstrate focal disc space collapse or endplate sclerosis and irregularities, depending on the severity of disc degeneration. Segmental loss of lordosis is often seen, typically due to muscular splinting from pain.



Figure 3: Sagittal cut of T2weighted MRI of the lumbar spine.

MRI is the imaging modality of choice for discogenic pain analysis. Injury to the disc is apparent, as the color of the disc itself changes, also known as a "dark disc". A normal intervertebral disc has a high water content, visually appearing bright on T2-weighted MRI sequences. In contrast, a degenerated disc has the appearance of loss of hydration which gives a darker color. Furthermore, the MRI will show if there is a high intensity zone (Figure 3). The high intensity zone indicates a tear in the annulus fibrosis that is highly specific for the cause of discogenic pain⁸.

The gold standard diagnostic test for discogenic pain is a discogram. In this test, contrast dye is injected into the painful disc(s) as well as a normal disc, used as a control under fluoroscopic guidance. Reproduction of the patient's pain during injection into the abnormal disc, but not the normal disc, is highly indicative of a symptomatically painful disc.

The quantity of injected dye as well as the dye pattern within the disc are important in diagnosing discogenic pain. A normal disc can accommodate only a moderate amount of fluid which stays contained within the interior of the disc, outlying the nucleus and being contained entirely by the annulus. A damaged disc, in contrast, accepts

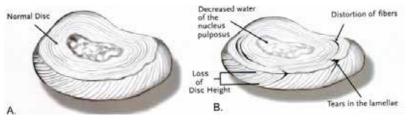


Figure 4: Comparison of a normal lumbar disc (A) with a degenerated lumbar disc (B.)

a larger amount of fluid and displays tracking through annular defects (Figure 4).

According to widely used classification methods, low grade dye tracking into the annulus may be normal in light of no pain reproduction. However, dye passage completely through the annulus, especially if it outlines a high intensity zone, is abnormal. Normal discs almost never cause pain during the test, whereas a painful disc gives a positive result 81% of the time⁹⁻¹⁰.

Once discogenic pain has been diagnosed, treatments in cases that have failed non-operatively are traditionally fusion of the problematic disc. While results have varied based on the study reviewed, success rates of 95% have been reported¹¹. Although a fusion procedure is the gold standard management for discogenic pain, regenerative medicine has been on the forefront of recent research endeavors.

Regenerative medicine involves injection of growth factors or growth cells into the area of damaged tissues, thereby inducing growth and repair of the injured disc. The two main types of injections are platelet-rich plasma (PRP) and stem cells. PRP comes from a patient's own blood and has the highest concentration of growth factors. The goal with PRP is to turn on the cells within the disc, thereby inducing healing and pain relief. Stem cells, in contrast, contain both the patient's own cells with the potential to grow into any body part and the growth factors to turn on healing. Theoretically, this would result in a higher healing potential when injected into the damaged intervertebral disc. The cells come from the patient's pelvis which has a high concentration of stem cells as well as growth factors.

Early results are promising. PRP has resulted in accelerated healing for treating extremity injuries, including osteoarthritis and tennis elbow, but has been less extensively studied in the spine ¹²⁻¹³. Clinical data for stem cell treatment of spine disc breakdown has shown promising results in animal data. In addition, injection into painful human intervertebral discs has been shown to decrease pain ¹⁴. In sum, injection of either stem cells or PRP may improve patients with discogenic pain and is a new, attractive alternative to surgery in many situations.

Though there are many causes of low back pain, there is a multitude of literature that supports the disc as a potential pain generator. Non-operative treatment is generally successful at achieving success while persistent symptoms warrant a thorough investigation of discogenic pain. While clinical examination and imaging are very useful, a discogram is the gold standard for diagnosis.

THOUGH EXCELLENT OUTCOMES MAY BE ACHIEVED THROUGH SURGERY, REGENERATIVE MEDICINE IS A RAPIDLY GROWING AND EVOLVING FIELD THAT MAY RESULT IN SIGNIFICANT PAIN REDUCTION AND RESTORATION OF FUNCTIONALITY.

References

- 1. Papageorgiou AC, Croft PR, Ferry S, Jayson MI, Silman AJ. Estimating the prevalence of low back pain in the general population: evidence from the South Manchester back pain survey. Spine 1995; 20:17.

 2. Anderson, GB. Epidemiological features of chronic low back pain.
- Lancet 1999; 354: 581-585.

 3. Degenais S, Caro J, Halderman S. A systemic review of low back pain
- 3. Degenais S, Caro J, Haiderman S. A systemic review of low back pain cost of illness studies in the United States and internationally. Spine J 2008; 8: 8-20.

 4. Boden SD, Davis DO, Dina TS, Patronas NJ, Weisel SW, Abnormal
- magnetic-resonance scans of the lumbar spine in asymptomatic subjects. A prospective investigation. JBJS Am 1990; 72(3): 403-408. 5. Peng BG. Pathophysiology, diagnosis, and treatment of discogenic
- back pain. World Journal of Orthopedics 2013; 4(2): 42-52.

 6. McKenzie R, May S. The Lumbar Spine: Mechanical Diagnosis and Therapy. 2 vols. Waikanae, New Zealand: Spinal Publications, 2003.

 7. Zbang YG, Guo TM, Guo X, Wu SX, Clinical diagnosis for discogenia.
- Inerapy. 2 vols. Walkanae, New Zealand: Spinal Publications, 2003.

 7. Zhang YG, Guo TM, Guo X, Wu SX. Clinical diagnosis for discogenic low back pain. International Journal of Biological Sciences 2009; 5(7):647-658.
- 8. Bogduk N, Aprill C, Derby R. Lumbar discogenic pain: state-of-the-art review. Pain Medicine 2013; 14: 813-836.
- 9. Weishaupt D, Zanetti M, Hodler J, Min K, Fuchs B, Pfirrmann CW, Boos N. Painful lumbar disc derangement: relevance of endplate abnormalities at MR imaging. Radiology 2001; 218(2).
- 10. Manchikanti L, Glaser SE, Wolfer L, Derby R, Cohen SP. Systematic review of lumbar discography, as a diagnostic test for chronic low back pain. Pain physician 2009; 12: 541-559.
- 11. Peng B, Chen J, Kuang Z, Li D, Pang X, Zhang X. Diagnosis and surgical treatment of back pain originative from the endplate. European Spine Journal 2009: 18: 1035-1040.
- 12. Filardo G, Kon E, Buda R, Timoncini A, Di Martino A, Cenacchi A, Fornasari PM, Giannini S, Maracci M. Platelet-rich plasma intra-articular knee injections for the treatment of degenerative cartilage lesions and osteoarthritis. Knee Surgery, Sports Traumatology, Arthroscopy 2011. 19(4): 528-535.
- 13. Mishra AK, Skrepnik NV, Edwards SG, Jones GL, Sampson S, Vermillion DA, Ramsey ML, Karli DC, Rettig AC. Efficacy of platelet-rich plasma for chronic tennis elbow. The American Journal of Sports Medicine 2013. 42(2): 463-471.
- 14. Pettine KA, Murphy MB, Suzuki RK, Sand TT. Percutaneous injection of autologous bone marrow concentrate cells significantly reduces lumbar discogenic pain though 12 months. Stem Cells 2015. 33:146-156.





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REGENERATIVE RESEARCH

Introduction

Regenerative medicine is a field still in its infancy, but there are already numerous methods being used to apply regenerative therapy in clinics. This article will provide an overview of some of the different categories of therapies. It will also provide a review of some of the clinical data examining the outcome of these regenerative therapies.

There is a broad category of regenerative therapies that are notably different from pharmaceutical-based therapies because of their use of living cells.

THESE CELL-BASED THERAPIES
CAN USE CELLS WHICH ARE EITHER
AUTOLOGOUS, IF THE CELLS ARE
HARVESTED FROM THE PATIENT AND
RETURNED TO THE SAME PATIENT,
OR ALLOGENEIC, IF THE CELLS ARE
HARVESTED FROM DONORS AND
DELIVERED TO THE PATIENT.

Cell therapies can be further classified by whether they are direct or indirect. A *direct cell therapy* provides cells that are directly involved in the healing process. An *indirect cell therapy* provides cells/proteins that supply signals to activate or attract other cells in the body to engage in the process of healing.

Autologous cell-based regenerative therapies have gained popularity in recent times because they are minimally invasive and are a low risk treatment option for treating various conditions. The use of platelet-rich plasma (PRP) is a wellknown therapy. Platelets are cells in the body that assist in local healing by aggregating to seal a wound and prevent bleeding. They also release a wide variety of proteins and growth factors that signal other cells. PRP treatments typically involve collecting and concentrating platelets from the patient's own blood. The PRP is delivered back to the area requiring treatment. The platelets then release growth factors that modulate inflammation and attract other cells to repair the tissue. This makes PRP an example of an autologous indirect cell therapy.

An example of an autologous direct cell therapy would be the use of concentrated bone marrow aspirate (BMA). Bone marrow aspirate is collected from the patient, concentrated, and delivered back to the area requiring treatment. Concentrated bone marrow aspirate, or bone marrow concentrate (BMC), contains platelets like PRP as well as a variety of cells involved



in the healing process, including neutrophils, monocytes, and other immune cells. These cells are directly involved in the healing process. Bone marrow is also a rich source of Mesenchymal stem cells (MSCs) and other progenitor cells in the body. MSCs have gained considerable notice in the research community for their ability to differentiate into various tissues, but MSCs have also been found to have numerous other functions, including the ability to modulate other cells through biochemical signaling¹. This signaling also includes anti-inflammatory and immunomodulatory effects. It has been postulated that these functions may play the greater role in the therapeutic effects seen with treatments using MSCs. Delivering stem cells directly to the affected region initiates the healing process and helps control inflammation. Furthermore, stem cells have anti-microbial, antiapoptotic, pro-angiogenic properties and help in matrix remodeling. Providing stem cells/BMC as a treatment can be considered a promising alternative to current standard of care practices.

It should be noted that in the area of cell-based therapies, only PRP and concentrated bone marrow aspirate are cleared under the FDA. Autologous platelet-rich plasma concentrate has been used for years, but concentrating bone marrow aspirate is comparatively more recent. Bone marrow aspirate is not considered to be a "human cells, tissues, and cellular- and tissuebased product" (HCT/P), which is a category of biologic materials that is regulated by the Public Health Service Act (42 USC 264; PHSA) sections 361 and 351. BMA is excluded under 21 CRF 1271.3, which states "minimally manipulated bone marrow for homologous use" is not considered a HCT/Ps. Bone marrow can be concentrated as long as the processing method meets the FDA standard for "minimal manipulation." The FDA has defined "minimal manipulation" for cells as non-structural tissues (e.g. BMA) as "processing that does not alter the relevant biological characteristics" (21 CRF 1271.3(f)(2)).

There are other cell-based therapies being explored that have not been approved for use by the FDA. One of these cell therapies is the use of MSCs harvested from adipose tissue.

Adipose tissue has been shown to be another

source of MSCs² and their frequency is observed to be higher than that of bone marrow³. Adipose-based cell therapy is a direct cell therapy and usually can be autologous or allogeneic, using cells harvested by lipoaspiration. There are numerous products on the market which use lipoaspirate and these can have FDA approval for indications, such as body contouring. Adiposebased cell therapy is not currently FDA approved for other indications. In the FDA's 2014 Draft Guidance for Industry "Human Cells, Tissues, and Cellular- and Tissue-Based Products (HCT/Ps) from Adipose Tissue: Regulatory Considerations", it was determined these applications of adipose-based cell therapies are for non-homologous use because adipose tissue does not perform this function in the donor. Using HCT/Ps from adipose tissue to treat bone and joint disease is generally considered a non-homologous use.

Research in adipose-based cell therapy is continuing and it will likely continue to develop the potential use of adipose-derived MSCs in the future.

At this point, we should note the difference between autologous and allogeneic cell therapies. While PRP and BMC are autologous cell-based therapies, there are cell therapies being explored using cells harvested from donors. These cells are often expanded in laboratories and frozen with a cryopreservative for delivery. Such therapies are not approved by the FDA because they go beyond the definition of "minimal manipulation". Consequently, the FDA has delivered warning letters to companies who have attempted to market these types of therapies.

Like adipose-based cell therapies, allogeneic-based cells will continue to be developed, but more research and regulatory work will be required.

There are other regenerative therapies being explored that do not utilize cells. These include prolotherapy⁴, which involves the injection of dextrose solution into joints and therapies based on material derived from amniotic sources⁵. Amniotic-based therapies have only been approved for wound dressing. These are indirect therapies because they do not use cells; rather, they seek to encourage the response of cells toward the healing process.

Cell Therapy Safety & Clinical Efficacy Data

In the earlier days of stem cell research, there was concern that therapies using stem cells could lead to the development of cancer. A large study was carried out in France where 1,873 patients were monitored for cancer incidence after BMC therapy. After following the patients for 12.5 years, the authors concluded BMC therapy did not increase cancer rates among patients when compared to cancer incidence in the general population during the same period⁶.

Several studies have proven the efficacy of BMC treatment. In one rotator cuff repair study, one group of patients (n=45) underwent a single row rotator cuff repair and BMC treatment. The matched control group (n=45) underwent the same technique of repair, but did not receive the BMC treatment. BMC injection was performed at the end of rotator cuff tendon fixation as well as injected into the tendon at the junction between the bone and tendon and in the bone. After a 10 year follow up, patients treated with BMC had 100% healing of rotator cuff tear at six months compared to only 67% in the control group. Interestingly, BMC injection prevented further ruptures during the next 10 years. At 10 years, 87% of the patients in the BMC group had intact rotator cuffs, compared to only 44% in the control group⁷. In another rotator cuff repair study, tendon integrity was demonstrated by MRI after BMC treatment, establishing the effectiveness of BMC treatment⁸

While treating atrophic tibial diaphyseal nonunion, bone union was obtained in 53 out of the 60 patients treated with BMC, establishing the safety and efficacy of this treatment.

In another study with a goal to treat discogenic back pain, 26 patients with 13 one-level and 13 two-level BMC disc injections experienced 73% reduction in VAS pain scores and 67% average improvement in ODI at three years¹⁰. A prospective, randomized study showed the equivalence between cancellous allograft mixed with BMC and autologous iliac crest bone, which is considered the gold standard for lumbar fusions. Notably, there was no statistical difference in fusion scores between allograft and autograft in the lateral gutters, interbody cages, or facet joints¹¹.

There is mounting evidence that BMC therapy is not only safe, but effective as well. The next step would be to design and conduct large scale clinical trials to gather larger data sets from a bigger population.

WITH THE EMPHASIS ON MINIMALLY INVASIVE TREATMENTS, REGENERATIVE MEDICINE THERAPIES ARE TAKING CENTER STAGE AND ARE BECOMING A FEASIBLE AND PROMISING TREATMENT ALTERNATIVE.

References

- 1. Murphy MB, Moncivais K, Caplan Al. Mesenchymal stem cells: environmentally responsive therapeutics for regenerative medicine. Exp Mol Med. 2013;45(11):e54. doi:10.1038/emm.2013.94.
- 2. Zuk PA, Zhu M, Ashjian P, et al. Human adipose tissue is a source of multipotent stem cells. Mol Biol Cell. 2002;13(12):4279-4295. doi:10.1091/mbc.E02-02-0105.
- 3. Kern S, Eichler H, Stoeve J, Klüter H, Bieback K. Comparative analysis of mesenchymal stem cells from bone marrow, umbilical cord blood, or adipose tissue. Stem Cells. 2006;24(5):1294-1301. doi:10.1634/stemcells.2005-0342.
- 4. Slattengren AH, Christensen T, Prasad S, Jones K. PURLs: Prolotherapy: a nontraditional approach to knee osteoarthritis. J Fam Pract. 2014;63(4):206-208.
- 5. Riboh JC, Saltzman BM, Yanke AB, Cole BJ. Human Amniotic Membrane–Derived Products in Sports Medicine. Am J Sports Med. 2016;44(9):2425-2434.
- 6. Hernigou P, Homma Y, Flouzat-Lachaniette C-H, Poignard A, Chevallier N, Rouard H. Cancer Risk Is Not Increased in Patients Treated for Orthopaedic Diseases with Autologous Bone Marrow Cell Concentrate. J Bone Jt Surgery-American Vol. 2013;95(24):2215-2221.
- 7. Hernigou P, Flouzat Lachaniette CH, Delambre J, et al. Biologic augmentation of rotator cuff repair with mesenchymal stem cells during arthroscopy improves healing and prevents further tears: a case-controlled study. Int Orthop. 2014;38(9):1811-1818.
- 8. Ellera Gomes JL, da Silva RC, Silla LMR, Abreu MR, Pellanda R. Conventional rotator cuff repair complemented by the aid of mononuclear autologous stem cells. Knee Surgery, Sport Traumatol Arthrosc. 2012;20(2):373-377.
- 9. Hernigou P, Poignard A, Beaujean F, Rouard H. Percutaneous Autologous Bone-Marrow Grafting for Nonunions.Influence of the Number and Concentration of Progenitor Cells; J Bone Jt Surg. 2005;87(7):1430.
- 10. Pettine K, Suzuki R, Sand T, Murphy M. Treatment of discogenic back pain with autologous bone marrow concentrate injection with minimum two year follow-up. Int Orthop. 2016;40(1):135-140.

 11. Johnson RG. Bone marrow concentrate with allograft equivalent to
- 11. Johnson RG. Bone marrow concentrate with allograft equivalent to autograft in lumbar fusions. Spine (Phila Pa 1976). 2014;39(9):695-700.





SPINAL RESEARCH FOUNDATION'S SPINAL HERO

Christopher R. Good, M.D., F.A.C.S.

Practice: Virginia Spine Institute

I am proud to be working with the Spinal Research Foundation and fostering its mission to improve spinal health through research, education, and patient advocacy. I care about this topic for many reasons, not only because I help patients as a spinal surgeon, but also because I grew up in a family that was forced to deal with spinal disease every day.

When I was just 10 days old, my very active father was involved in a fall from a chairlift at the ski area he managed in Colorado. He fell about 30 feet, landing on his feet, crushing multiple bones in his back. At that time, treatment options were limited; he underwent a major back surgery and was placed in a body cast for many months. One of my first childhood pictures of my dad was a picture of me sitting on his full-body cast as he lay in bed. It is an understatement to say that spine surgery at that time had very limited success and although my childhood was filled with many wonderful times, his disability and progressive condition was a constant struggle for us. My father ultimately passed away as a result of his injuries when I was in sixth grade.

Based on my childhood and my father, I always planned to enter the medical field and moving into the specialty of spine surgery was a natural choice for me. I'm constantly amazed by the tremendous breakthroughs that have taken place over the last forty years and I only wish that my father could have received the benefits of the treatments we have available today. In 2014, his treatment would have resulted in a totally

different outcome than when he went through treatments. Improvements in surgery, therapy, medicines, and other techniques have truly revolutionized the difference we can make in people's lives.

One great example of the breakthroughs that are occurring is the advancements in the field of regenerative medicine and I am very happy to be featured in this issue of the SRF journal as a "Spinal Hero." While my mild injury pales in comparison to what my father went through, I would like to share my own personal success story with regenerative medicine.

I got my love for the outdoors from my parents, including anything that has to do with the mountains or with fishing. While on a family vacation in 2015, I injured my knee when I slipped and fell on a boat while fly-fishing for Tarpon in North Carolina. For anyone who has never flyfished, fly casting commonly involves standing on a platform on a small boat, looking for fish and casting. On this trip, I was lucky enough to hook a once-in-a-lifetime Tarpon, arguably one of the most athletic fish in the world. Trying to reel in a fish of this size and strength is similar to trying to reel in a professional football player and in the epic two-hour struggle, I had to step off the casting platform. When I landed, I slipped, felt a "pop," and had instant pain in my knee.

The most important thing is that I was able to get the epic fish to the boat and safely release him, but in the process, I tore my Medial Collateral Ligament (MCL), an important ligament that stabilizes the inside of the knee (Figure 1). Some people would say that I am only telling this story as an excuse to show a picture of me with this amazing fish (can you blame me??), but this started my struggle with the injury.

I saw my good friend, Dr. Niteesh Bharara, a physiatrist at the Virginia Spine Institute and an expert in rehabilitation and regenerative medicine. Luckily, he told me that most MCL tears like mine are expected to heal with time and physical therapy. With that good news in hand, I started working with two great physical therapists from Virginia Therapy & Fitness Center (VTFC) (Nicki and Casey) as well as a home exercise program. Unfortunately, as time went on, it became clear that I was not healing as hoped.

I could walk all day and luckily my ability to see patients and perform surgery was not an issue at all, but I could not get back to exercise or any activity that required me to twist or pivot on my leg. I even had pain trying to get onto the floor and play with my kids!

AS THE MONTHS WENT ON, I FAILED TO IMPROVE DESPITE DOING ALL THE "RIGHT" THINGS.

Ultimately, Dr. Bharara recommended that we try an injection of platelet rich plasma (PRP) to the MCL tear as well as prolotherapy along the rest of the ligament to try to stimulate a healing response. I have been using PRP for a few years for certain spinal injections and have been happily surprised with how well it has worked, so I decided to give it a try. PRP is a substance taken from a patient's blood stream. To get PRP, blood is taken from a patient, just like donating blood. This blood is then prepared in a centrifuge which spins the blood very quickly, helping to separate the blood in to its various components (Figure 2). PRP is the component of the blood that contains a type of blood known as the platelet as well as growth factors associated with tissue healing. This substance can be injected into a damaged area (muscle, ligament, disc, cartilage) to try and stimulate a healing response.



Figure 1: Tear of the Medial Collateral Ligament (MCL) of the knee.

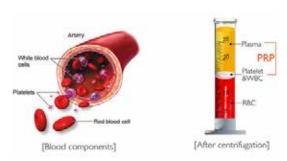


Figure 2: Various components of the blood before and after being centrifugation.

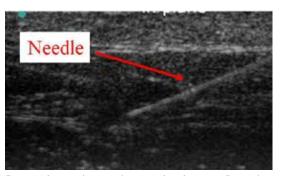


Figure 3: Ultrasound imagery being used to place a needle into the ligament for PRP/Prolotherapy.



In the procedure, a needle was placed into my ligament under ultrasound and the PRP/ Prolotherapy was injected into the damaged ligament (Figure 3). I can tell you with certainty that he hit the spot when he injected the PRP. Not only did I watch the needle go into the MCL tear on the ultrasound, I felt the exact pain I usually got and I knew he had the spot!

As I tell my patients who are thinking about having any regenerative therapy, healing after the injection takes some time and it was no different for me. I was extra sore in the knee for about two weeks and once this calmed down, I started my dedicated PT and exercise routine all over again. Around six weeks after the injection, I was starting to worry that it was not going to work,

(IT'S IRONIC THAT I AM ALWAYS TELLING MY PATIENTS AT THIS TIME THAT PATIENCE IS KEY!)

but finally started to notice slow improvements in my pain. I continued to heal for at least four months after the injection, ultimately getting over 95% improvement in my pain! I went back to full exercise and activities, including playing with my kids without any pain. Now over 1 1/2 years out from the injection, an ultrasound cannot even find evidence of a tear in my MCL and I am able to do the things that I love again. Last winter, I was even able to carry a very heavy pack on a high mountain trek in the Chugach Mountains of Alaska!

I would like to say a big "thanks" to Dr. Bharara and the team who helped me! I hope that my story helps to inform and inspire other patients who are going through an injury similar to mine. Regenerative medicine helped me get back to the highly active lifestyle that I love!

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Sabrina M. Woodlief, B.S.Spinal Research Foundation





Virginia Spine Institute (VSI) and Spinal Research Foundation (SRF) have partnered together on a project called SpineOnline, a web-based research tool created to document outcomes of spinal treatment. Now more than ever, quality data is needed to preserve access to appropriate spinal health care and to drive improvement. SpineOnline brings together patients and the nation's top spinal practitioners to identify what works best in treating spinal disorders. This secure national database provides a simple and intuitive user experience for providers and patients from any online access point! SpineOnline produces outcomes research by integrating health care providers' clinical evaluation and patients' selfreported outcomes to improve spinal health care across America. The design of this research tool is focused on accumulating patient and provider input so as to most rapidly collect essential data to advance spinal health care, a very personal part of our mission here at VSI and SRF.

SpineOnline uses the same forms as you would typically fill out in-house, but we are finally at the beginning of our electronic transitioning phase and hope that you join us in this exciting endeavor if asked to participate! Not only is this an environmentally conscious change, it should also help save you time.

YOU CAN ACCESS YOUR FORMS AT THE CONVENIENCE OF YOUR HOME (OR OTHER MOBILE DEVICES), WHICH WILL HELP FOCUS YOUR VISIT ON YOU AND YOUR DOCTOR, RATHER THAN YOU AND YOUR FORMS.

You'll have secure, online access to your account and everything will be confidential to you and your doctor. Collecting this pre- and post-op data on a large scale will also help others with similar conditions to yours. By presenting this collective information to the insurance companies, we hope that they will start covering these types of procedures and treatment options because they do, in fact, produce sound and valid positive outcomes. Without this data, patients are going to continue losing access to life-improving therapies.

We are very proud of the work that we've accomplished so far in this ambitious and innovative treatment outcomes project, but there's still more to be done to help prove what works, to drive innovation, and to reduce the uncertainty associated with spinal treatments. We thank you for your support and involvement and look forward to continued success!

If you would like to learn more about SpineOnline, please contact the System Administrator, Sabrina Woodlief, at swoodlief@spinerf.org.













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to learn how to get involved - through sponsorship opportunities, registration, and how to become a Spinal Champion!







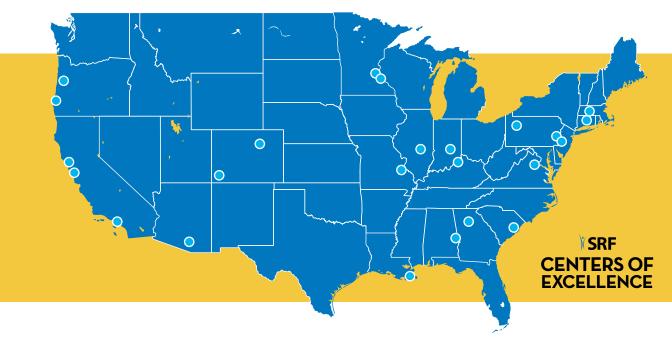




spi·nal cham·pi·on noun \spī-n²l cham-pē-ən\

a person who has achieved an improved quality of life through treatment for back or neck pain.





The Spinal Research Foundation has named 26 Research Partners across the country that share one core mission: improving spinal health care through research, education, and patient advocacy.

These centers offer the best quality spinal health care while focusing on research programs designed to advance spinal treatments and techniques.



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The Spinal Research Foundation was founded in 2002 and exists to prove what works, to drive innovation, and to provide hope for all those who are affected by back and neck pain. We have been hard at work finding answers that help people return to the activities and people they love.

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