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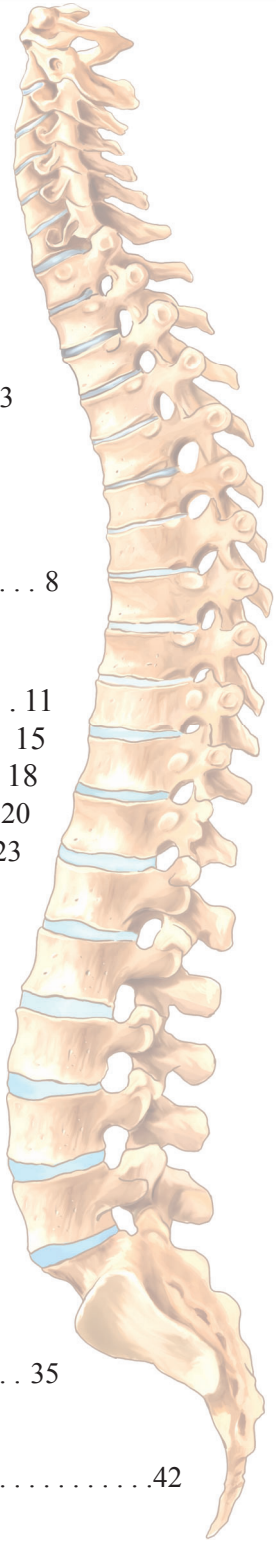

From the Editor

Brian R. Subach, M.D., F.A.C.S.

The Epidemic of Obesity: Disturbing Trend and Public Health Concern

Obesity is a national health crisis. If current trends continue, it will soon surpass smoking as the biggest single factor related to early death, reduced quality of life, and added health care costs in the United States. According to the Centers for Disease Control and Prevention (CDC), one-third of adults in the U.S. are obese; another third are overweight, with Americans getting heavier as each year passes. Obesity is responsible for more than 160,000 premature deaths per year, as reported by a study in the *Journal of the American Medical Association*. The average obese person costs society more than $7,000 a year in lost productivity and added medical treatment combined, say researchers at the George Washington University. Added medical costs for a person 70 pounds or more overweight may amount to as much as $30,000 in a lifetime depending on the individual's race and gender.

These societal implications make answering the following question all the more urgent: Why is it so easy to gain weight, yet so difficult to lose those extra pounds? The answer seems relatively obvious; simply consume fewer calories than you expend, resulting in net energy expenditure and theoretically, weight loss. This basic formula for weight loss is simple and has been presented in various ways by hundreds of salesmen looking to make a quick buck from people who are desperate to lose weight. Although it seems straightforward, in reality, achieving weight loss proves to be both challenging and anxiety-provoking, which is why population based surveys report obesity as the nation's number one lifestyle-related health concern. For a species that evolved to consume high calorie foods in an environment where famine was a constant threat, maintaining a healthy weight should be easy, but it is often complicated by lifestyles too busy to allow for healthy cooking. In addition, we are constantly inundated by media messages depicting happy, thin people seated in fast food restaurants. No person, regardless of his/her size, is immune to the marketing geniuses. Nearly everyone who tries to diet seems to fail in the long run. A review of 31 diet studies carried out by the American Psychological Association (APA) in 2007 found that as many as two-thirds of dieters end up weighing more two years later than they did before they attempted their diets.

Table 1. BMI Formulas and Calculations.[1]

Measurement Units	Formula and Calculation
Kilograms and meters (or centimeters)	Formula: weight (kg)/[height (m)]^2 Since height is commonly measured in centimeters, divide height in centimeters by 100 to obtain height in meters. Example: Weight = 68 kg, Height = 165 cm (1.65 m) Calculation: 68 ÷ (1.65)^2 = 24.98 BMI = 24.98
Pounds and inches	Formula: weight (lb)/[height (in)]^2 × 703 Calculate BMI by dividing weight in pounds (lbs) by height in inches (in) squared and multiplying by a conversion factor of 703. Example: Weight = 150 lbs, Height = 5′5″ (65″) Calculation: [150 ÷ (65)^2] × 703 = 24.96 BMI = 24.96

What is BMI?

Body Mass Index (BMI) is a number calculated from a person's height and weight. For most people, BMI is a fairly reliable indicator of body fat content. BMI does not measure body fat directly, but research has shown that BMI correlates with direct measures of body fat, such as underwater weighing and dual energy x-ray absorptiometry (DEXA scanning). This makes BMI measurements reasonably accurate, while being less time-consuming and less costly than direct body composition measurements. Additionally, BMI is an inexpensive and easy-to-perform screening method, which any health care practitioner can perform.

Why Does CDC Use BMI to Measure Overweight and Obesity?

Calculating BMI is one of the best methods for population assessment of overweight and obesity. Because calculation requires only height and weight, it is inexpensive and easy to use for clinicians and for the general public. The use of BMI allows people to compare their own weight status to that of the general population.

Table 2. Standard Weight Status Categories Associated with BMI Ranges for Adults.[1]

Body Mass Index (BMI)	Weight Status
Below 18.5	Underweight
18.5–24.9	Normal
25.0–29.9	Overweight
30.0 and Above	Obese

Among adults age 20 or older in the United States, 154.7 million are considered overweight by our current definition (BMI of 25.0 kg/m^2 or higher); this number is comprised of 79.9 million men and 74.8 million women. Of these 154.7 million people, 78.4 million (approximately half) meet the criteria for obesity (BMI of 30.0 kg/m^2 and higher)—36.8 million men and 41.6 million women.

What are the Consequences Associated with Obesity in Adolescents and Adults?

- Hypertension
- High Cholesterol
- Type 2 Diabetes (non-insulin dependent)
- Coronary Artery Disease
- Stroke
- Gallbladder Disease
- Osteoarthritis
- Sleep Apnea and Respiratory Problems
- Some Cancers (endometrial, breast, and colon)

How Does Obesity Affect Health Care Costs?

Total excess costs related to the current prevalence of adolescent and adult overweight and obesity is estimated to be 254 billion dollars. Of that amount, 208 billion dollars is due to lost productivity secondary to premature morbidity and mortality, and 46 billion dollars is directly related to increased medical costs.

According to Marion Nestle, PhD, MPH, Chair of the Department of Nutrition and Food Studies at New York University, the costs of these illnesses will be "astronomical." If current trends and the growth of obesity continue, total health care costs attributable to obesity could reach 861 to 957 billion dollars by 2030, which would account for 16 to 18% of U.S. total health care expenditures.

James O. Hill, PhD agrees. Hill, Director of the Center for Human Nutrition at the University of Colorado Health Sciences Center, claims that at the rate we're going, obesity-related diabetes alone "will break the bank of our health care system." One has to wonder how obesity got so out of control that we reached this crisis point. More importantly, how do we change societal behaviors which have brought us to this place?

First, what is causing the epidemic? Not surprisingly, everyone agrees that it stems from two things: eating too much and exercising too little. The differences of opinions are in the specifics. Although people may toss around the idea of genetics in obesity, genes can't really explain what's happening, Hill says. While a person may have a genetic predisposition toward a certain body type, the fact that each succeeding generation is heavier than the last proves that changes in our environment are playing the key role. Hill believes the culprit may be a decrease in our physical activity, arguing that because of shifts in how we live and work, we don't get as much exercise as previous generations did.

Nestle agrees that exercise is important, but she lays more stress on eating habits. In her book, *Food Politics: How the Food Industry Influences Nutrition and Health*, Nestle argues that recommendations about healthy eating are overwhelmed by the hun-

[1]Tables 1 and 2 are adapted from: "About BMI for Adults" Healthy Weight. Centers for Disease Control and Prevention, 13 Sept. 2011. Web. 17 Feb. 2014.

dreds of billions of dollars worth of advertising for junk foods that we're subjected to at home and even in public schools. Additionally, as fast food chains compete with one another by increasing portion sizes, our waists are increasing proportionately.

Despite the new attention paid to obesity by doctors, researchers, and the media, no discernible progress has been made in fighting obesity. According to most experts, it looks almost certain that obesity will get worse before it gets better.

So What is the Solution?

1. Reduce your caloric intake, increase your water intake, and make healthy choices.
2. Add more activity to your daily routine (take the stairs instead of the elevator) or enlist a personal trainer.
3. Consider using a therapist or support group to get you through the difficult times (it's harder to go at it alone).
4. Consider medications to help (for example, Orlistat, which blocks fat absorption). Discuss this decision with your doctor.
5. Consider bariatric (weight-loss) surgery if your BMI is over 40 or if your BMI is over 35 and you have additional medical problems, such as diabetes. Speak with your physician about your options.

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From the President

Thomas C. Schuler, M.D., F.A.C.S.

Advancements in Spinal Treatments and Future Trends

Frequently, I am asked what is new and exciting in spinal care. I am excited to share with you some new technologies that we believe will eliminate pain and improve function. Disc regenerative therapies, artificial discs, robotic surgery, and improved minimally invasive surgery are some of the most promising recent advances currently available.

Twenty years ago, spinal treatment options were severely limited and often ineffective. However, throughout the past two decades, spinal health care has experienced exponential growth and improvement. The reason for this explosive growth, during which spinal health care emerged from the dark ages, is that spinal surgery became recognized as its own specialty. Surgeons, forming this specialty, increased collaborative efforts which fostered new technologies, quality research, and enhanced education. The opportunity for such rapid, monumental improvement in the field existed because its starting point was so low. Consequently, the contemporary spinal health care treatments that are available today dwarf the success of treatments in the past and allow physicians to greatly improve the lives of their patients.

Attempting to heal an injured or degenerative disc is an exciting goal that we are rapidly approaching. We are now able to use a patient's own blood's products to stimulate healing. Platelet rich plasma (PRP) and stem cells are two products that show promise. PRP is obtained by centrifuging 60cc's of a patient's blood, thereby aggregating the platelets and growth factors into a layer which can then selectively be used for injection. Once the PRP is collected from the patient's own blood, it is injected into the injured disc to initiate healing. Thus far, we have not seen complete resolution of symptoms, but many patients experience a sustained 50% reduction in their symptoms. Considering the alternatives to either live in pain or undergo a major surgery, PRP treatment is an intriguing option.

The use of stem cells has also shown great potential. Stem cells are obtained by aspirating the bone marrow from the bone of a patient's pelvis. This bone marrow is then centrifuged, producing a layer of growth factors and primitive stem cells. These cells, which have the potential to differentiate into any type of tissue, are then injected into the disc, as in the PRP model. So far, of the two, the use of stem cells looks to hold the most promise for improving disc regeneration, but time and research will tell. We are also encouraged by the results we have seen from employing PRP and stem cells to heal other spinal ligamentous and fascial injuries. With these exciting new options, we hope to minimize or eliminate the amount of surgery needed to heal patients.

While advancements like PRP and stem cells have made great strides toward improving the lives of patients suffering from spinal problems, government policies and refusals on the part of insurance companies to pay for these types of treatments create major roadblocks in the ability to provide these new options to the public. Insurance companies call these treatments "experimental," and the burden of payment falls entirely on the patient. Financially, this limits patients' access to these novel and exciting treatments.

Artificial discs (spine arthroplasty) are changing the way we surgically manage spine problems. When a patient has intractable back pain and an injured or degenerative disc has been shown to be the source of the pain, traditionally a fusion has been the best treatment option. Advancements in minimally invasive surgery and improved implant technology have made fusion surgery highly successful. However, for select patients, preserving motion while eliminating the painful disc may be a better option. Combining fusion at one level and artificial disc at another level creates a hybrid construct and is even more useful. I believe so strongly in this technology that one year ago I had two artificial discs and a fusion performed in my own neck to alleviate years of suffering. I can say that one year later, it works great, and I am back to all my activities.

Unfortunately, both political and financial roadblocks limit more widespread application of arthro-

plasty and hybrid technologies as well. We have seen some increased coverage by insurance companies, but the decisions have been slow and don't cover the most useful applications of multiple levels and hybrid constructs.

Minimally invasive surgery continues to be refined and expedites a patient's recovery. Robotic spine surgery and image guidance technology are both great advancements which now enable the surgeon to insert instrumentation through smaller incisions. If surgery is necessary, a less invasive operation is better for the patient both short-term and long-term.

Recently, the rate of new technologies and advancements has slowed. Some of this deceleration is caused by a flattening of the learning curve, but a significant amount is being caused by the roadblocks set in place by political forces as well as denial of coverage by insurance companies. Obamacare policies are disincentivizing medical device manufacturers from bringing new technology to the marketplace in the United States. These companies are pursuing new technology internationally where the road to market is more conducive to successful product development.

I am excited to see what research proves to be the safest and simplest means of resolving patients' suffering. Happy, pain-free, active people are good for themselves, their families, and their communities. Disc regenerative therapies, artificial discs, robotic surgery, and improved minimally invasive surgeries hold great promise for the future lives of suffering patients. It is important to realize, though, that all the advancements and improvements are only beneficial when they are able to be applied to those in need. Support from both government and insurance organizations is essential.

The evolution of spinal health care is only half the battle; the other half lies in the hands of the government and insurance companies. Their decision to either support or continue to block access to these advancements ultimately affects patients. I hope that as research continues to showcase these advancements, patients will have access to these life improving technologies.

Overview

Anne G. Copay, Ph.D. and Carrie B. Califano

The three components of the mission of the Spinal Research Foundation (SRF) constitute the focus of the spring 2014 issue of our Journal: research, education, and patient advocacy. Advocacy is highlighted as a critical element of SRF's purpose, giving patients an opportunity to share their experiences of suffering from spinal disease and finding relief through spine treatment. Five patients have shared their stories in our Spine Tales, describing the success they had overcoming their neck or back pain to inspire hope in other patients and display the effectiveness of treatments. Laura Bologna discusses SRF's national *We've Got Your Back* race series that provides spinal patients the chance to set and achieve goals of physical accomplishments. Finally, our advocacy efforts work toward preserving patients' access to care. In *Insurance Denials are on the Rise!*, Dr. Christopher Good clearly describes insurance companies' tactics to refuse to pay for necessary treatments in order to improve their bottom lines at the expense of the patient's well-being.

The intention of SRF's educational efforts is to empower patients with knowledge about overall health and spinal health. In the *From Your Personal Trainer* feature, Melissa Treat, R.N., B.S., C.P.T. explains the importance of strong core muscles to provide support to the spine. She also describes several exercises to help strengthen the core muscles. Dr. Brian Subach, in his *Editor's Note*, addresses the unfolding obesity epidemic. He describes the inexorable increase in the number of obese adults and children with the dramatic consequences of obesity on their health. Overall, each issue of the *Journal of the Spinal Research Foundation* fulfills the mission of educating patients: it constitutes a source of current and useful information about spinal health.

Research evaluates the developments in the field of spinal health such as updates on current techniques, new and future treatment options or diagnostic tools, treatments under investigation, and new findings about spinal pathology. Our expert Dr. Christopher Yeung gives us his perspective on the importance of research for patients and physicians alike. Dr. Paul Slosar provides a research update on the advancements in spinal fusion implants, summarizing the impact of modifying the surface of titanium implants to improve clinical outcomes. In *Use of Antibiotics to Treat Low Back Pain*, Dr. Michael Hasz discusses the possible role of infections in causing back pain. Additionally, Dr. Hasz also writes on the effects of Vitamin D deficiency in spinal health.

Through continued collaboration and support of spinal patients, our Research Partners, and generous donors, SRF will continue to revolutionize spine care and carry out its mission: Improving Spinal Health Care through Research, Education, and Patient Advocacy!

Anne G. Copay, Ph.D.

Dr. Copay studies the outcomes of surgical and non-surgical spine treatments. She published several articles on the outcomes of spine fusion. She has ongoing research projects concerning the effectiveness of new spine technologies and the long-term outcomes of surgical treatments.

Carrie B. Califano

Ms. Califano serves as the Clinical Research Coordinator at the Spinal Research Foundation (SRF). She manages the integrity of SRF's clinical trial data, monitors adherence to research study protocols, and provides technical support for SpineOnline, SRF's web-based research platform. Ms. Califano holds a B.S. degree in Human Biology from Cornell University and has conducted research projects with Duke Sports Medicine Center and EXACT Sports in Chicago.

Ask the Expert

Christopher A. Yeung, M.D.

Q1: Why is research crucial to improving spinal health care?

There is always room for improvement in everything we do, and spine treatment is no exception. Research helps us determine which treatments are most effective and supports the development of better treatment options, as well as less invasive ways to perform classic proven treatments.

Q2: What studies or trials have you participated in that resulted in improvement of spinal treatment?

The Desert Institute for Spine Care (DISC) was recently a primary FDA site for the Coflex® Dynamic Interspinous Stabilization Device clinical trial. This device was recently FDA approved just over a year ago as a result of the clinical trial. The Coflex® device provides dynamic stabilization as a less invasive, motion sparing alternative to lumbar fusion. The data showed equivalent improvement in pain and disability scores, with less stress at the adjacent levels compared to fusion. This represents a major accomplishment in spine care.

Q3: What can spinal patients do to become more knowledgeable about spinal health?

Beyond consulting with your physician about questions and concerns you may have regarding your spinal health, the internet can be used as a great resource to learn more about spinal problems and available treatments. Two very reliable websites that I recommend are spineuniverse.com and spine-health.com.

Q4: How can physicians and patients help to preserve access to the best spinal health care available?

Physicians need to support their patients and fight the ever increasing insurance denials of appropriate care. More quality research is needed to prove the effectiveness of common, established treatments to fight these inappropriate insurance denials. Patients need to become knowledgeable about their spine problems and their treatment options. Patients who have benefited from spine surgery or other successful interventions need to be vocal about it to help preserve that same treatment as an option for future patients.

Christopher A. Yeung, M.D.

Dr. Christopher Yeung is a board certified, fellowship trained orthopedic spine surgeon at the Desert Institute for Spine Care in Phoenix, AZ. He has a special interest in minimally invasive spine surgery techniques with a philosophy of choosing the least invasive yet most effective method to treat spine problems. Dr. Yeung treats the full spectrum of degenerative and traumatic spinal conditions, and he has been the principal investigator in many FDA studies for artificial disc replacement and fusion alternatives. He speaks nationally and internationally on the latest, most innovative treatment options in minimally invasive spine surgery and has published numerous articles. In addition, Dr. Yeung is the team spine surgeon for the Arizona Diamondbacks, the Los Angeles Dodgers, the Cincinnati Reds, and the Arizona Rattlers. He was recognized by his peers to be one of the top Phoenix spine surgeons in 2009, 2010, 2012 and 2013.

We've Got Your Back Race for Spinal Health

Laura A. Bologna

The Spinal Research Foundation proudly hosts the only run/walk event in the country designed to celebrate the accomplishments of Spinal Champions. A Spinal Champion is someone who has suffered from back or neck pain and has overcome it through either nonsurgical or surgical treatments. Spinal Champions are celebrated on race day with commemorative race shirts and a special tent where they can share their stories of success. As the *We've Got Your Back* Race spreads to more locations, the focus of the event continues to be the celebration of Spinal Champions, emphasizing their accomplishments after they have regained their lives.

At SpineCare Medical Group's 4th annual *We've Got Your Back* Race in San Francisco, one of Dr. Slosar's patients, Raf, shared his story. "I had excruciating pain down my right leg. I couldn't walk, and I even had to use a cane. But a week after my back surgery, I could walk again, and my life changed. Today I'm here to run as proof! Dr. Slosar gave me my life back. Not only did he repair me, but I think I'm better than I was before. I'm here at the race to prove to everyone that surgery *can* be a good option, and I hope to inspire others!"

> **"I couldn't walk, and I even had to use a cane. But a week after my back surgery, I could walk again, and my life changed. Today I'm here to run as proof! Dr. Slosar gave me my life back."**

Since the *We've Got Your Back* Race, Raf has completed a Half Iron Man Competition and continues to exercise regularly without pain. Another one of Dr. Slosar's patients, Mary, had never competed in a race before she experienced her back pain, but she says, "I decided to take my life back after my surgery. I started running competitively, so here I am today

Young Runners at the 2013 WGYB Event in San Francisco Enjoy a Delicious Treat After the Race.

NFL player Larry Fitzgerald at the WGYB Race in Arizona Supports SRF's Efforts to Raise Awareness for Spinal Health.

running in the *We've Got Your Back* Race!" Now in its fourth year, many Spinal Champions return to the San Francisco race annually as a testament for how far they've come since their surgeries, and most importantly, to share their stories with others and raise awareness.

In New Orleans, Southern Brain and Spine had their local police squad come out for the 2nd *We've Got Your Back* Race in support of Dr. Thomas and the entire practice. They have been treating officers and giving them their lives back so the squad can resume their work for the city after suffering from debilitating back pain.

Similarly, the first ever *We've Got Your Back* Race in Scottsdale, hosted by Desert Institute for Spine Care (DISC), had the local S.W.A.T. team in attendance showing their support for the cause. Special guest and eight-time Pro Bowler Larry Fitzgerald of the Arizona Cardinals emphasized the importance of raising awareness for such a critical issue. "We're here for a great cause. This race continues to grow nationally every year, and personally I have a lot of family members with chronic pain throughout their spines; it's very common. This is really why we are all here, and it is important to know there are people out there like these DISC surgeons who can help."

Former Scottsdale Police Commander, Jay Schwartz, was Honorary Chair of this inaugural event and spoke to the crowd about this special experience. "You can see the big turnout. I have been able to talk to several other patients and hear what we've been through. It's amazing the degree of pain we have all experienced, and the way patients have been able to overcome it with the help from these doctors." The enthusiasm around the *We've Got Your Back* Race is growing rapidly. The race director in Scottsdale, Susan Parker, wrapped up her event by saying, "We have barely even finished the first year, and we're already talking about the second. We are excited to grow!"

The Spinal Research Foundation continues to host a variety of events to promote awareness about our cause and celebrate the continued successes of our Spinal Champions. For upcoming race dates and more information about our events please visit us at wevegotyourbackrace.org.

Laura A. Bologna

Ms. Bologna is the National Events and Development Coordinator at the Spinal Research Foundation (SRF). She is responsible for coordinating the foundation's *We've Got Your Back* Races for Spinal Health, managing the organization's fundraising activities, and supporting SRF's social media. She holds B.A. degrees in Public Relations and History from Penn State University.

SPINAL RESEARCH FOUNDATION'S

WE'VE GOT YOUR BACK

RACE FOR SPINAL HEALTH

Celebrate Spinal Champions & Healthy Spines!

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SRF

5K RACE &
1 MILE FUN RUN

Benefiting

Spine Tale
Lauren Downey

Brian R. Subach, M.D., F.A.C.S.

My back pain first started while I was on a band trip to Florida during my sophomore year of high school. I learned you could go to the front of the line at Disney World if you're in a wheel chair. After my trip, my primary care physician ordered x-rays and instructed me to take some muscle relaxers and rest. Unfortunately, the x-rays were inconclusive, but the pain continued to get worse. A few months later, I had an MRI done, and after reviewing the results, my doctor recommended I go see a specialist. The orthopedic surgeon told me and my parents, who went with me to all my appointments, that she didn't know how I was able to walk around due to a very large disc herniation. When she asked what I had done to cause this large two level herniation in my lower back, I had no answer. I hadn't been in a car wreck or done anything that could have caused this horrible pain. It had come on gradually and got progressively worse as time went on. The doctor felt that I needed to have surgery immediately, and we scheduled my first back operation ten days from that appointment. Not long after, my herniation had reoccurred, requiring a second surgery that was performed by a neurosurgeon; much physical therapy was required for my recovery.

I was able to walk across the stage to receive my high school graduation diploma and made plans to begin college in the fall. My parents felt it was important for me to stay close to home because I was still having back pain and continued to see the neurosurgeon for checkups. I was learning to live with constant pain, thinking it would always be something I would have to put up with everyday. As I entered my second year of college, the pain I had been trying to ignore was starting to cause me to spend more and more time in bed when not in class. I decided the pain was becoming unbearable again. After reviewing another set of MRI's, the doctor said the herniation was so severe that he was very concerned I could suffer drop foot. This time the surgeon wanted to perform two new tests, an EMG study and a CT scan. The first test they'd done that day didn't show anything severe enough to be causing me that much pain. He called back the next day, reporting that the second test showed severe damage requiring yet another surgery. Trying to express to others the intense pain I was in when it's not something they can visibly see always made me feel that people thought I was overreacting. The frustration and doubts were another set of symptoms that accompanied the pain.

A few years after my third surgery I was still living with pain and taking medication daily, but I tried once again to move on with my life. When I wasn't working, I would be in my bed trying to find any relief I could. I couldn't hang out or take road trips with friends; the pain would just get too overwhelming. My parents were beside themselves watching me deal with all this, and feeling frustrated that we could find no solution to alleviate this life altering pain. Our next effort was to get a consultation at a reputable facility. I had a great doctor who was very kind, and I felt I had a good connection with him. He said he would operate once again, but still could not give us any guarantee that this would take away the pain. After the surgery, I had finally experienced relief from the constant pain. I was so excited and hopeful that I could finally have an almost normal life. I would always have some pain, but maybe this time it wouldn't become so extreme.

I had about six wonderful months before the pain started coming back once again. During this time, I was diagnosed with fibromyalgia, a chronic pain disorder, and a new cocktail of pills prescribed by a rheumatologist was added to my daily intake of medica-

tions. I had also developed persistent neck pain after the third surgery.

One of my mom's friends recommended the Virginia Spine Institute, and we scheduled an appointment with Dr. Brian Subach. Anyone who has seen Dr. Subach knows what a fun sense of humor he has, but also how he listens to what you have to say. He doesn't talk down to you or make you feel that what you are dealing with can't be as bad as you describe it. He, along with his wonderful physician assistants Matt and Diana, truly make you feel that you are in good hands. This time, the problem would require neck surgery. You would think that after all the failed back surgeries, I wouldn't think of going through it again with my neck, but I really trusted Dr. Subach and his plan for taking away this pain. I am happy to say he was successful! It was amazing how much better my neck felt after a two- level fusion surgery. To this day, my neck is still not causing me that initial pain I was going through.

After my neck pain had been relieved, I once again was back at the drawing board to address my continued back pain. I started to go though different tests and MRI's to find out the current condition of my back. Dr. Subach felt that there was a lot of scar tissue and doing another surgery wasn't going to fix the problem. After nearly nine years of constant pain, little to no exercise, and extended periods of bed rest, I had gained a lot of weight. I repeatedly heard that losing weight would help with the back pain, but despite trying numerous weight loss plans, nothing seemed to help. In addition to the ongoing deep depression I had been dealing with, losing weight was not something I was able to do on my own.

In the next chapter of my life, I was found eligible for disability. That process took over two years to be approved and included a lot of stress and court appointments. However, once that process was completed, I then had Medicare which thankfully would pay for gastric bypass surgery, something Dr. Subach had recommended. This was the most painful recovery I have ever been through in my life; not only was my back in constant pain, but my abdominal area was in horrendous pain from the bypass procedure. Eventually I was able to start walking and doing a little exercising. As the months went by, I was amazed to see a totally different person looking back at me in the mirror. On the one year anniversary of the bypass surgery, I had lost a total of 170 pounds since my initial visit to the doctor. Feeling better about myself helped take away some of the depression and anxiety I had been going through, but I still had nonstop back pain and returned to Dr. Subach's office for a consultation.

Dr. Subach recounts his clinical evaluation of my lumbar spine:

"Lauren had been suffering from back and bilateral leg weakness and numbness for the past ten years. When asked to grade her pain, she stated that it was a nine on a visual analog scale of ten in terms of severity. She reported that there were no specific injuries which lead to this, however, spinal disorders did run in her family.

The EMG study of her legs demonstrated not only the presence of chronic nerve damage in the right L5 and S1 nerve distributions, but also acute denervation of moderate severity in both of those nerves as well. Her lumbar MRI scan and x-rays demonstrated obvious degenerative changes involving the L3/L4, L4/L5, and L5/S1 disc spaces with evidence of a mobile spondylolisthesis at L3/L4. She underwent lumbar discography to better evaluate the disc spaces and there was evidence of concordant and positive pain reproduction from L2/L3, L3/L4, L4/L5, and L5/S1 with obvious degenerative changes at each level.

Having had previous lumbar spinal surgery with evidence of instability at L3/L4 along with evidence of progressive nerve damage at L5 and S1, she was a candidate for additional spinal surgery. In general, when the problem is compression of the nerves and instability, it requires a decompression and stabilization operation. We discussed the options, including anterior lumbar surgery and posterior lumbar surgery. Although it would be a significant operation, her quality of life was such that she could not exist without pain medications, and she was essentially disabled because of the discomfort."

Dr. Subach and his team spent a lot of time talking about the pros and cons of going through this type of

Spine Tale: Lauren Downey

surgery. Over and over again, I was told that it may not fix the pain, it might even be worse afterwards. Once again, I had such faith in Dr. Subach that I felt I needed to try this last (hopefully) procedure which might give me a chance of a normal life if it worked.

Dr. Subach's explains my operation and recovery:

"In conjunction with her family, she made the decision to pursue operative intervention and underwent surgery in September 2012. The surgery that she underwent, called a transforaminal lumbar interbody fusion (TLIF), at the L3/L4, L4/L5, and L5/S1 levels involved removing each of the degenerative discs, restoring disc space height and normal posture with devices placed into the disc spaces, and decompressing each of the spinal nerves, particularly the right L5 and S1 nerve roots which were showing evidence of progressive damage.

In a four-hour operation requiring a few days of recovery in the hospital, Lauren tolerated the operation extremely well and was sore; however, she noticed that her back felt stronger immediately. When I saw her at two weeks after surgery, her pain level was down to a two on a scale of ten. She continued to have some mild discomfort and some numb sensation in the legs, but she felt that she was already doing better than she was prior to surgery despite the size of the intervention. By June 2013, nine months out from the surgery, she had continued mild discomfort around the area of her incision most likely related to the hardware, specifically with increasing activity. Overall, she was much improved.

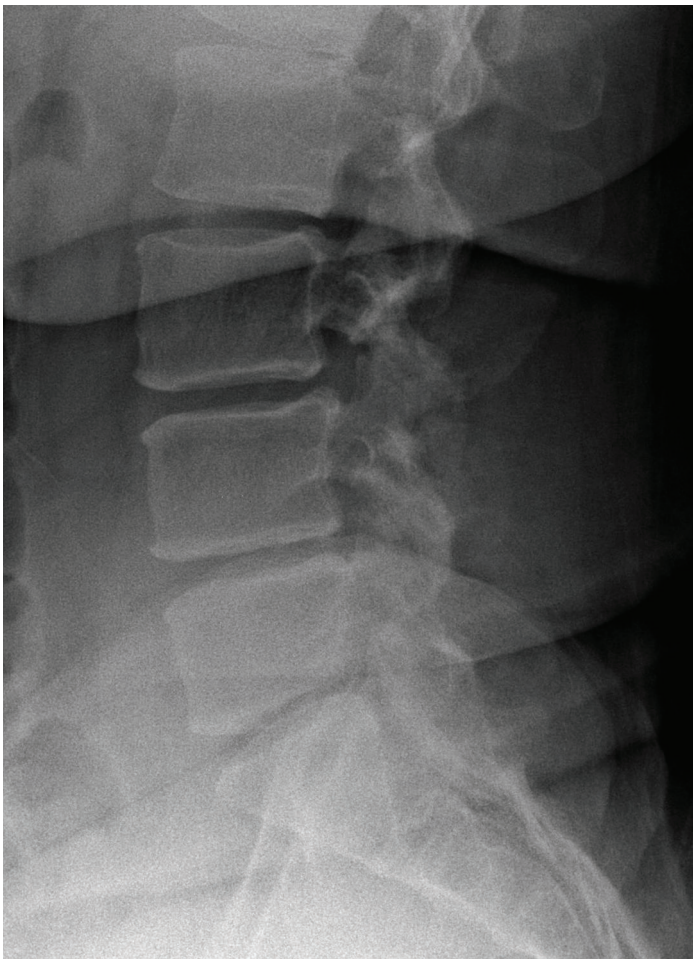


Figure 1. Pre-operative Lateral View X-ray of the Lumbar Spine.

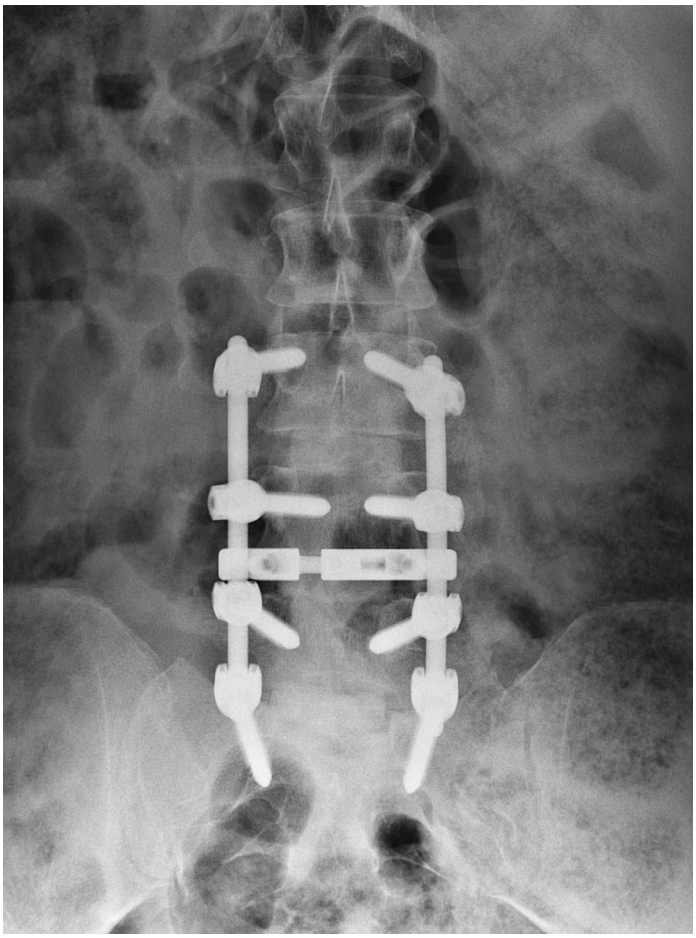
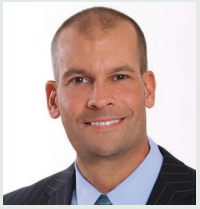


Figure 2. Post-operative Anteroposterior View X-ray Following a TLIF at L3/L4, L4/L5, and L5/S1.

Lauren had undergone four previous surgical interventions prior to this extensive reconstruction procedure. She is now able to exercise and be more active, and, for the first time, she feels that she has her life back. Not only does credit go to Lauren, but also her family who was a significant support system throughout the previous operations as well as this more recent procedure."

While I may not be able to do the limbo, my back feels so much better. I can't believe it's true. I really don't know how I survived all those years with the excruciating pain. I am so thankful for everything Dr. Subach and his team have done for me. I am now able to do all the things I missed out on over the past ten years; I've ridden in my brother's race car during a drifting event, gone tubing down the river, driven for hours in the car enjoying road trips, taken long walks on the Manassas battlefields with my dog, and participated in life like I was never able to do before. My goal is to be able to participate in the *We've Got Your Back* 5K race this year. Thank you so much to Dr. Subach a very talented, skilled, caring doctor with an amazing team who make such an amazing difference one patient at a time.



Brian R. Subach, M.D., F.A.C.S.

Dr. Subach is a spine surgeon and the President at the Virginia Spine Institute. He is a nationally recognized expert in the treatment of spinal disorders and an active member of the American Association of Neurological Surgery, the Congress of Neurological Surgeons, and the North American Spine Society. He is a Fellow in the American College of Surgeons. He lectures extensively regarding the management of complex spinal disorders in both national and international forums. He is the Director of Research and Board Member for the Spinal Research Foundation and Editor-in-Chief of the *Journal of the Spinal Research Foundation*. He has written 15 book chapters and more than 50 published articles regarding treatment of the spine.

Spine Tale
Paul Satterfield

Brian R. Subach, M.D., F.A.C.S.

The onset of my spinal symptoms included itching on my arms and back of my neck, muscle weakness, stiffness, aching, lack of sleep, and constant pain in the back of my neck down to between my shoulder blades. Prior to meeting Dr. Subach at the Virginia Spine Institute, I decided to address these symptoms with another surgeon who performed an anterior cervical fusion back in October 2007. However, the surgery was unsuccessful, and the physical pain returned.

Soon after surgery, I started my own business. This induced much anxiety, because although the pain was becoming unbearable, I couldn't neglect work. The pain and anxiety had an effect on my family as well. I was not myself physically, and to concentrate on anything else in life was getting harder. I found no relief no matter what position I was in- standing, sitting, or lying down. Knowing that my quality of life was affected due to the daily battle with pain, I was forced to make an appointment with a specialist.

A year after my initial surgery, when the pain and other symptoms had returned, I found Dr. Subach for a consultation. He recounts his examination and findings:

"Paul initially presented to me describing 80% neck pain and 20% symptoms into his arms, specifically left-sided neck achiness and right arm numbness. The constant pain in his neck radiated down toward the left shoulder and he also had numbness in his right forearm down to his right thumb. He had similar symptoms in 2007 involving the left arm, which resolved after an anterior cervical fusion was attempted at C3/C4, C4/C5, and C6/C7.

On examination, flexion forward of the cervical spine caused pain, although extension to thirty degrees caused no discomfort. Light touch sensation was normal in both upper and lower extremities and on neurologic testing his reflexes were brisk, 3/4 in both the arms and legs. There was a Hoffmann's sign present bilaterally, indicating damage or compression of the spinal cord in the neck.

Having a presumptive diagnosis of cervical degenerative arthritis with previous attempted surgery and recurrent neck pain, my concern was one of two possible diagnoses; there was either a failure of the fusion to heal properly or there was progression of disease to involve a previously normal level. He had x-rays done at our office which demonstrated failure of the bone grafts to heal in the disc spaces where the fusion had been attempted. There was clearly plate fixation on the front of the spine, however, there was also a clear gap between the donor bone and the endplate confirming a pseudarthrosis, or false fusion. Essentially, instead

Figure 1. Lateral View X-ray of the Cervical Spine Following Anterior Cervical Fusion in 2007, Prior to Revision Surgery with Dr. Subach.

of healing solid bone, scar tissue finds its way into the area and there is continued motion. The bending x-rays demonstrated that the area of the attempted fusion still moved.

His MRI scan demonstrated evidence of signal change or a white area in the substance of the spinal cord, which indicated compression of the spinal cord and damage. In this area, there was spinal stenosis, which was significant and needed to be addressed."

Previously, I had tried several different non-operative treatments including chiropractors, massage therapy, physical therapy, pain relievers, traction, and a previous surgery for this same issue. Dr. Subach shared his recommendations and the procedure we decided to pursue:

"I discussed with Paul the two problems that I saw. The first problem was the failure of the fusion to heal properly, which meant that he would need a revision operation from the front side of the neck. My second concern was his forward flexed posture and persistent spinal stenosis which would require a decompression from the back of the neck. I discussed doing this in two phases: on day one, a posterior cervical laminaplasty to make sure the spinal cord had adequate room and on day two, plate removal followed by revision anterior cervical fusion placing a single plate across the front of the spine.

On January 3, 2011, he underwent a posterior cervical decompression laminectomy and fusion. At the time of surgery, I had planned to do a laminaplasty procedure, which would have given the spinal cord additional room but kept the supporting ligaments. During that attempted procedure, he developed an acute deterioration in his somatosensory evoked potentials and motor evoked potentials while he was on the table. That meant that my manipulation of his spinal cord was causing him to lose function in both his arms and legs.

Therefore, I decided to change the procedure from a laminaplasty to a decompression laminectomy, which would certainly be faster. Upon completion of the operation, he did move both his legs as well as the right arm. His left arm did not move initially but began moving shortly after starting the corticosteroid protocol for spinal cord damage. Paul made a reasonable recovery in both his legs and arms. We had excellent decompression of the spinal cord, however, he still had the pseudarthrosis to deal with. After waiting nearly two months for him to recover, he was taken back to surgery on March 16, 2011 to undergo revision anterior cervical fusion. I removed the previous plates, chiseled out the failed bone grafts, and revised his fusion, restoring his normal posture, his normal alignment, and decompressing the spinal cord beautifully. He had no problems with this operation, from positioning to wake up and was moving his arms and legs.

Over the ensuing months, Paul obviously had discomfort, which gradually improved with physical therapy and time. His ability to use his arms and legs

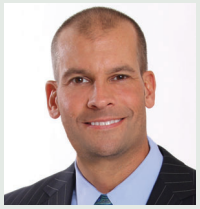
Figure 2. Post-operative Lateral View X-ray Following Revision Anterior Cervical Fusion from C3 to C7.

continued to improve, and by the time I last saw him in December 2012, he had absolutely no neck pain and had recovered normal function in his arms and legs. He essentially required revision surgery for a difficult problem, became transiently paralyzed on the operating table, regained his function, underwent anterior cervical reconstruction, and is now pain-free and perfect!"

Finding Dr. Subach changed my life drastically. I no longer need pain medicine on a daily basis; the itching and pain down my arms and back of my neck are gone. Since surgery, I now have more range of motion than even before surgery. I can do the physical labor necessary for my business without having to stop due to pain. Sleeping through the night is now possible. I am able to walk and participate in recreation with my

kids, like a game of football, riding dirt bikes, and my favorite past time drag racing. The anxiety I felt before surgery due to not seeing any relief in sight is a thing of the past.

I would recommend to anyone going through similar issues with chronic pain to please consider a consultation with a specialist, such as Dr. Subach. He looks at a patient as a whole, not just a number on a chart. He takes into consideration your family, lifestyle, work, and recreation. Dr. Subach gives the patient respect and the time needed to absorb the prognosis. If surgery is not necessary, he will point you in the right direction. Dr. Subach will give you back your life.



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Spine Tale
James Hagey

Nima Salari, M.D.

As a 77 year old school bus driver, part of my job requires that I routinely perform pre-trip systems checks to ensure that everything is working properly. One Friday morning, I was inspecting the clearance lights because we begin work while it's still dark outside. A single light in the back of the bus was being temperamental, so I began walking towards it down the empty parking lane beside me. I was looking up at the lights, not watching where I was stepping, and suddenly tripped and hit my head on the bus next to me. I got a large gash on my head that hurt terribly. I went to clean it up and get ready to leave when I noticed pain shooting down both my arms. I began flailing my arms to try to stop the intense pain.

Another bus driver called 9-1-1, and I was taken over to Scottsdale Healthcare Shea Medical Center. They stitched up my eye and ran some tests to figure out what was causing the severe pain that had migrated into both of my hands and fingers. Dr. Salari was on call at the hospital when I was admitted. He recalls his findings from the diagnostic tests:

"Mr. Hagey had numbness, pain, and weakness immediately in both arms along with a gash on his head. In the hospital, his symptoms did improve slightly, but he still had severe paresthesia and weakness associated with both hands. CT and MRI scans indicated an extension distraction injury involving the C6/7 level, and he was clinically exhibiting central cord syndrome. He also appeared to have significant stenosis in his cervical spine at the level above, C5/C6. We spoke about everything and decided to proceed with surgery. What made the case a little more complex was an aberrant vertebral artery on the left side with a history of carotid endarterectomy on that

Figure 1. Post-operative Lateral View X-ray Following Anterior Cervical Discectomy and Fusion at C5/C6 and C6/C7.

Figure 2. Post-operative Anteroposterior View X-ray Following Anterior Cervical Discectomy and Fusion.

side, which dictated a right sided only approach. We decided to do a two level anterior cervical discectomy and fusion (ACDF)."

Dr. Salari made sure I completely understood the procedure and his plan. He performed the surgery on Saturday, the day after my accident. I did so well that I was released to go home the following day.

Dr. Salari was an absolute blessing. I don't have any feeling of discomfort in my neck; the pain is just nonexistent. I have a little bit of tingling and cold/hot sensations in my finger tips, but it's nothing compared to what I was experiencing at the point of injury. It's so strange to see the titanium plate and screws in my neck. I don't even know it's there until I look at the x-rays! That intimidation or fear of working on my spine wasn't even a concern. The pain that I was experiencing had to be fixed.

I was able to get right back to work, and although I had been concerned about being able to play golf again, Dr. Salari said I can play. I have no fear of any activity. I'm also looking forward to doing yard work and getting the landscaping fixed up at our home in the valley this spring.

It was just amazing and wonderful to have the group at DISC come to my rescue. I told my family and peers that the caliber of care they provide is unmatched. I'm so pleased with that organization and can't express enough how fortunate we are that Dr. Salari showed up. DISC hosted a Spinal Research Foundation's *We've Got Your Back* 5k run and 1-mile walk that I participated in. The involvement the entire practice had at the event was really amazing. I met another gentleman at the event who also had spinal surgery, and this man was mighty grateful of that crew. I said, "I'm with you!"

Figure 1. James celebrating as a Spinal Champion at the SRF *We've Got Your Back* Race hosted by DISC on February 8, 2014.

Nima Salari, M.D.

Dr. Salari is a fellowship trained orthopedic spine surgeon with specialized training in the operative and non-operative treatment of pathologic conditions affecting the spine, including degenerative disc disease, scoliosis and other deformities, infections, and tumors. He has an interest in minimally invasive, tissue sparing approaches and image guided technologies in the management of spinal disorders. In addition to his clinical work, Dr. Salari has been involved in various orthopedic research projects involving the musculoskeletal system. He is a member of many professional organizations, including the North American Spine Society, and the American Association of Orthopaedic Surgeons. In his free time, Dr. Salari enjoys travel, various sports activities, and spending time with his family.

Spine Tale
Lorraine H. Gatling

Michael W. Hasz, M.D., F.A.C.S.

On a beautiful, warm afternoon in December 1999, my husband Wade and I were strolling along a quaint, brick path when suddenly I fell head-first onto my face. One person, who rushed to my aid, a nurse, insisted that I remain motionless because I had suffered a severe blow to my head as well as trauma to my neck and facial contusions. As a result of that fall, I was placed on the Virginia Brain Injury Registry. Over the next two years, I underwent three orthopedic surgeries and extensive physical therapy. It was at the end of this period that I was diagnosed as having foot drop and was referred to Dr. Hasz at the Virginia Spine Institute (VSI).

What impressed me first about VSI was its welcoming and friendly staff. When I met Dr. Hasz, I was experiencing mild to moderate spine pain. Following examination and a comprehensive tutorial on the spine, I was referred to physical therapy and pain management. Despite several non-operative treatments, over time my pain worsened. Dr. Hasz and I then agreed that I needed surgery to relieve the pressure on my spinal cord. Immediately after the decompressive lumbar laminectomy procedure, I was thrilled because the pain was at last gone!

Unfortunately, within months, I tearfully reported new symptoms; the result, my first spinal fusion. At that point, I feared that I was becoming a forever spine patient, sustained by therapy, pain management, and surgery, and VSI may soon become part of my extended family. I began reading extensively about spinal conditions to learn as much as I could about my diagnosis.

There were periods during my journey when the pain in my legs and back was so severe that I could barely walk, sit, or sleep. To put my mind in a pleasant place, I began to watch travel shows and read travel brochures. When I mentioned my expanded interest in travel during an appointment, my new family strongly encouraged Wade and me to get away. At that moment, travel became the fourth component of my health and wellness program.

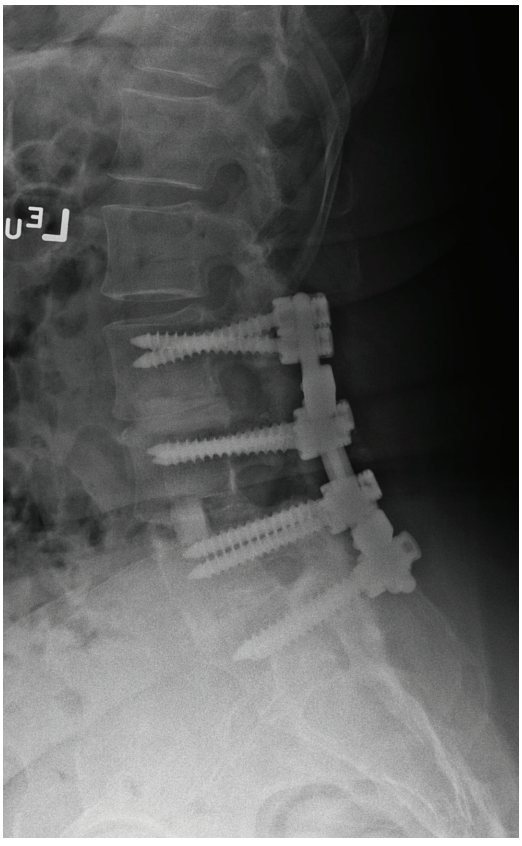


Figure 1. Lateral View X-ray after a Transforaminal Lumbar Interbody Fusion at L3/L4 and L4/L5 and Posterolateral Lumbar Fusion at L3/L4, L4/L5, and L5/S1.

Spine Tale: Lorraine Gatling

In 2009, we traveled to Zurich to visit friends, with plans to continue on to Paris for a week. Dr. Hasz prescribed medicines for me to carry, just in case. Unfortunately, on the last night of our Swiss visit, at the conclusion of dinner with family friends, my foot drop intruded, and I fell, again, face-first. I spent the next three days in Zurich University Hospital before returning to Georgetown University for repair of an occipital orbital fracture.

The next year I returned to VSI to reevaluate my back. Dr. Hasz recalls his examination and the procedure that we had decided to pursue.

"Lorraine presented with back and leg pain, made worse with standing and walking but better with sitting down. Her x-rays demonstrated that she had instability in her lumbar spine (called spondylolisthesis) and her MRI demonstrated the severe pinching of the nerves (called spinal stenosis). Her surgery was a decompressive lumbar laminectomy to take the pressure off the nerves as well as a fusion surgery to help stabilize the instability caused by the spondylolisthesis. Once her fusion healed one year later, we were able to remove her hardware (rods and screws supporting the back of the spine)."

Per VSI guidance, wearing my TENS unit, and toting my RX bag, I enjoyed two more trips to Europe and cruises throughout the Caribbean and from Miami to San Francisco via the Panama Canal.

In October 2013, Dr. Hasz performed a fourth procedure, this time on my neck. He reports his clinical evaluation and the operation:

"Mrs. Gatling also had cervical issues—neck pain, arm pain, tingling, and numbness, as well as symptoms consistent with early spinal cord injury called myelopathy. She had significant spinal stenosis identified on her MRIs. Due to her progressive and worsening symptoms, she underwent multilevel cervical surgery. She had an anterior cervical decompression and fusion. This surgery was able to take the pressure off her spinal cord and the nerves in her neck, and the fusion was able to stabilize and better align her neck. After this cervical surgery, her neck pain and arm symptoms were significantly improved."

Figure 2. Pre-operative Lateral View X-ray of the Cervical Spine.

Figure 3. Post-operative X-ray Following an Anterior Cervical Interbody Fusion at C3/C4, C4/C5, C5/C6, and C6/C7.

This was the easiest surgery to endure. I do my therapy and wear my bone stimulator and neck collar. I now have as much range of motion as before. One of the greatest outcomes of my surgical journey is that I now have full use of my dominant left hand. In fact, Wade and I recently hosted a grand dinner for twelve guests. I know my limitations, but with the support of my husband and my VSI family, life is wonderful.

Michael W. Hasz, M.D., F.A.C.S.

Dr. Hasz is a spine surgeon at the Virginia Spine Institute. He is board certified by The American Board of Spine Surgery, a Fellow in the American Academy of Orthopaedic Surgeons and a member of both the American Association of Orthopaedic Surgeons and the North American Spine Society. He was Chairman of the Department of Orthopaedic Surgery and Director of Spinal Surgery at the Andrews Air Force Base/Malcolm Grow Medical Center in Maryland. He currently holds an appointment as Clinical Instructor of Orthopaedic Surgery and Assistant Professor of Surgery at the Uniformed Services Health Science University in Bethesda, Maryland.

Spine Tale
Joseph E. Kasputys

Michael W. Hasz, M.D., F.A.C.S.

While training with my ice dancing partner for a national competition in early September 2012, I had a very hard fall, resulting in two broken ribs on my left side. Having broken bones while training at least seven times before, I didn't think too much about it and continued our training. A few weeks later, we entered four events at Adult Nationals in Las Vegas and won three gold medals and one silver medal. This was particularly satisfying since I was competing in a category open to anyone 25 years of age and older, and I was 76. Much of the credit should go to my partner, who is much younger than I and a spectacular skater.

Shortly after this fall on the ice, I began to experience sharp pains in my right sacroiliac joint and down my right thigh. In October it became much more difficult to skate, both in keeping my balance and in having the strength in my right leg to propel myself down the ice. I sought medical advice from the head of the neurosurgery department of a well-known Boston medical facility. Despite treatments with anti-inflammatory medications and physical therapy, the pain in my right hip and leg only became worse. By November it became difficult to walk and difficult to sleep, and by December I had to use a wheelchair to cover any distance. Not making progress at the Boston medical facility, I sought consultations with Dr. Michael Hasz at the Virginia Spine Institute as well as a head neurosurgeon of another world-famous hospital. Through these consultations, I learned how badly deteriorated my spine had become, all beginning with scoliosis from birth. My decades of hard use had worn down a number of the discs.

There were a number of options discussed to improve my condition, but I elected the most conservative, which was a discectomy at L3/L4. The head of neurosurgery at a famous hospital in a nearby city performed the surgery. He had anticipated a thirty minute operation, but it required three and one-half hours since he found very tightly stretched nerves over the disc protrusion, which required extreme caution to free up. This operation successfully relieved my pain. However, after the surgery, I had almost no control over my right leg and the muscles in that leg had atrophied, all due to the stretched and damaged nerves. After discharge from the hospital in early January of 2013, I embarked on an aggressive program of physical therapy, determined to regain full use of my damaged right leg.

About six weeks into this program of therapy, I began to have pain in my left sacroiliac joint and left leg. This pain quickly became quite severe. From March through May, I received several epidural injections which provided only short-term relief, and I steadily became worse. The neurosurgeon who performed the first operation suggested that four discs be removed and the vertebrae be fused—a very big operation, with a long recovery period. This seemed very aggressive, and I searched for alternatives that might be less drastic. I flew to Zurich to consult with a leading doctor about disc replacement, using a technology approved for use in Europe, not yet approved by the FDA here in the United States. I also consulted again with Dr. Hasz at the Virginia Spine Institute. The pain in my left hip and leg became increasingly severe, and in July I began to experience intense pain in my lower spine. I had to discontinue all physical activity and use a wheelchair for mobility. I also experienced intense pain at night even when I was lying quietly in my bed.

These symptoms drastically changed my life. I enjoy athletic activities immensely. I typically train at ice dancing for one to two hours per day, five days per week, and compete in national and regional competitions. I enjoy skiing and mountain biking, and usually

work out in a gym two to three times per week, alternating with rowing on a stationary rowing machine. For a number of years, I have entered the world championship stationary rowing competition in Boston, which attracts competitive rowers from countries all around the world. I also love ballroom dancing and some adagio, involving lifts and drops.

Summit of Mt. Kilimanjaro, the Highest Peak in Africa. Photo Taken January 2011.

A few years ago I took up mountain climbing. I started out training in the White Mountains of New Hampshire, doing mostly winter climbs in ice and deep snow. This was a valuable opportunity to learn the basic techniques of climbing, use of ropes, ice axes, crampons, overnight camping in cold weather, etc. I then proceeded to train further in the Rocky Mountains, learning to carry a heavy backpack and increasing the weight until I could readily handle 50 pounds through a daylong climb. I then became more adventurous, and climbed the highest mountains in Africa (Kilimanjaro), Europe (Elbrus in Russia) and Antarctica (Mt. Vinson). Mt. Vinson was really exciting, since we spent nearly two weeks in Antarctica. Our team of three climbers and a guide spent six days conquering the mountain, with the four of us being all alone, over 250 miles from the nearest Antarctic research station. When we reached the summit, the temperature was 45 degrees (Fahrenheit) below zero, with the wind chill an estimated 85 degrees below zero. When we returned, I learned that at age 75, I was the oldest person ever to summit that mountain.

In addition to physical activities, I've frequently traveled internationally for business since the late 1970's. From 1987 until 2000, I was the Chairman and CEO of Primark Corporation, a public company listed

Climbing the Highest Mountain in Antarctica, Mt. Vinson.

on the New York Stock Exchange, which at the time was one of the five largest companies headquartered in the greater Washington, D.C. area. I even owned a flat in London for convenience since I traveled almost weekly to Europe to look after the Primark subsidiaries that were headquartered there. In 2000, I sold Primark and founded what became the world's largest economic information and forecasting company, Global Insight, Inc. Global Insight tracks the economies of over 180 countries around the world and has offices in practically every major country, from Singapore to Beijing, Johannesburg to Abu Dhabi, and Sao Paolo to Bangalore, increasing my amount of required

travel. After selling Global Insight in 2008, I have been founding and investing in start-up companies, again, typically with an international dimension. Indeed, one is headquartered in Beijing and another has most of its staff in Russia and India.

Accepting a Distinguished Performance Award from the Committee for Economic Development at the Waldorf Astoria in Nov 2013.

My spine problems brought everything to a halt. I still tried to exercise some, but was largely unsuccessful. My ice dancing, ballroom and social dancing, skiing, mountain biking, and mountain climbing simply had to stop. I cut way back on international travel, and when I did travel, I could only go through the airport in a wheelchair. It was an effort to go anywhere or do anything, and I had to cope with constant pain. I was provided painkillers, but the side effects were very unpleasant. I did not know if I would ever regain my strength or mobility, and I developed a huge amount of respect and consideration for those who have to put up with such limitations and pain all the time.

Dr. Hasz recalls his evaluation of me:

"Mr. Kasputys initially presented with very severe pain that resided in his right hip, anterior thigh, and radiated around the groin and towards the knee and anterior shin as well. These symptoms are very consistent with a pinched nerve or that of acute radiculopathy. His x-rays and MRI, however, demonstrated that he also had scoliosis in the lumbar spine in addition to pinched nerves due to stenosis. Scoliosis is a curve in the back that leads to advanced degenerative changes and subsequent disc herniations and stenosis. The nerves which appeared to be irritated the most were identified at the middle of the lumbar spine at the major part of the curve in his back.

Mr. Kasputys sought many opinions concerning his treatment in the U.S., as well as overseas. European recommendations included a fusion as well as an artificial disc replacement. Neurosurgical recommendations in the U.S. included a long extended fusion from the lower thoracic level down to the pelvis.

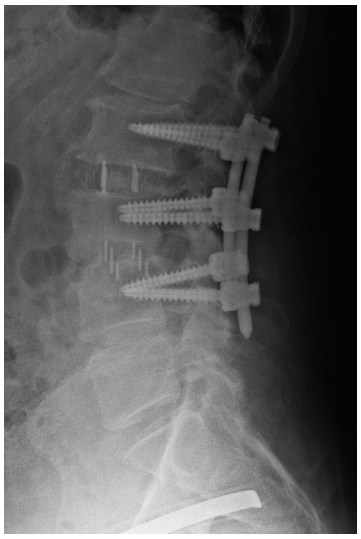
The surgical options I discussed with him included a large surgery with the major goal of realigning the scoliosis as well as decompressing the nerves. An alternative treatment was to perform a minimally invasive surgery, focusing on the areas that appear most consistent with his symptoms, involving a much smaller surgery at the L2/3 and L3/4 levels. This would not significantly decrease the curve in his back, but since he had this curve for many years and remained very active, I recommended that he undergo the minimally invasive surgery, focusing on what appeared to be his major symptoms at the L2/3 and L3/4 level. Mr. Kasputys was also aware that this minimally invasive surgery would not prevent him from undergoing the larger surgery to address his degenerative scoliosis, if it proved necessary in the future. However, we were very optimistic that this wouldn't be the case."

After much discussion, Dr. Hasz and I agreed to take the more conservative route. He performed an XLIF, which is an extreme lateral interbody fusion procedure with posterior instrumentation that removed the deteriorated discs and L2/L3 and L3/4, inserting spacers with bone graft material to fuse these three vertebrae. This operation allowed him to decompress the nerves through an indirect approach, stabilize the mid-portion of my scoliosis, and allow the nerves to heal.

My nerve pain had immediately improved by the day following this operation. Two days later, I had stage two of the pre-planned surgery to install rods for stability from L2 to L4. Following this procedure, I again embarked on a program of physical therapy for rehabilitation, first performing exercises in water and then moving to increasingly more challenging exercises at the PT facility and at the gym.

Achieving the SRF Mission

Lateral View of Pre-operative MRI Showing Degeneration at L2/L3 and L3/L4.



Lateral View of Post-operative X-ray Following an XLIF from L2-L4.

Simply put, my treatment has restored my life from pain and limitations to new opportunities, the possibility of accomplishment, and fun.

After being in pain and on the sidelines for about fifteen months, the most important factor improving my quality of life is that I am nearly pain-free. The pain initially started with discomfort, but quickly moved to very severe and limiting. My only residual problems now are occasional pain and numbness in my right knee. However, this pain is fleeting and transitory, and is nothing for which I would take medication.

Being essentially pain-free, I now feel very liberated. However, I have to recognize that my spine still has weakness, still has a curve, and is potentially fragile. Dr. Hasz did reduce the curve by about one-third, but he could only do further reductions by doing additional fusions, which neither of us thought was a good idea.

I resumed ice dancing about four and one-half months after the operation performed by Dr. Hasz. While I don't skate with the speed, strength, and balance that I previously had, my skating is measurably improving with every week that goes by. I am not doing anything that requires lifting my partner, but I hope to get back to that some day. In the meantime, I am enjoying my skating, and our goal is to compete in the 2014 Adult Nationals, which will be held in Pasadena in October.

I am also back doing ballroom and social dancing again. For now, my dance and life partner only lets me do very small and easy lifts. She is so light that I could do more, but I don't want her to worry. I am back doing gym workouts, but generally using free weights that are 20–30% lighter than before. I have been steadily increasing weight, but I am careful not to load my spine too much. I am also back to stationary rowing. When I first started rowing again, I was just doing 2,000 to 3,000 meters at a slow pace. I am now rowing 5,000 meters (plus warm-up and cool-down) in under 22 minutes. I feel very fortunate to be back into a regular rowing routine.

I don't know if I'll ever climb a big mountain again, but at least I can hike and climb up small ones. I proved that to myself just a few weeks ago when I climbed Mt. Pierce in New Hampshire. I climbed in snowshoes in reasonably deep snow, and reached the summit in three and one-half hours. This was not a serious climb or great time, but it was a big step for me. I am going to keep climbing modest mountains, which gets me outdoors and in beautiful scenery.

Vicki Van Mater and I doing a ballroom dance exhibition.

I have now gone skiing four times this year. I used to go down the black diamond trails and enjoyed the challenge of the moguls. However, having been warned to be careful, I now stay on the groomed slopes and concentrate on form. I am having fun doing that. I have also done some road bik-

Spine Tale: Joseph E. Kasputys

At the Summit of Mt. Pierce Approximately 4½ Months after Spine Surgery.

ing, and feel perfectly capable of going out on a mountain bike on easier trails.

Guess what? I can touch my toes, even with the rods in my back. Even better, after my operation I am one and one-quarter inches taller having regained height I lost from my collapsing spine.

As far as business is concerned, I am back doing long distance international travel with no problems. In the past couple of months, I have been to China, Europe and Africa. I have been a Trustee of the Committee for Economic Development (CED) for nearly thirty years, and was its co-chairman from 2008 to 2011. I am now back to actively working with the CED, which includes meetings, speeches, and visits to key legislators on Capitol Hill to promote measures that will help the U.S. economy to grow faster and provide everyone with more opportunity. This work is very important to me, and I am glad to be more involved again.

At the first sign of back or neck pain, it is important to learn as much about your options as soon as possible. I would recommend consulting with your regular doctor and with specialists to choose a course of treatment that seems right, weighing the benefits, costs, and risks. It is most important to recognize that such treatments, while not without some level of risks, can bring real relief and vastly improve the quality of your life. This has certainly happened to me. I really think the improvement in my condition is amazing.

I would strongly recommend anyone seeking treatment for back and/or neck pain to give serious consideration to the Virginia Spine Institute (VSI). I have experienced treatment and evaluations from top doctors and medical facilities from Boston to Zurich to Baltimore, and I find that the Virginia Spine Institute really stands out. The doctors are first rate, and every person on the staff treats patients professionally and considerately. Everyone is very knowledgeable and helpful, and I always received a full explanation of every option, risk, and issue. When it comes to caring for your spine, you really want to go to people you can trust. I trust the people at the VSI.

My impression of the goal of VSI is to get their patients "back in the game," whatever that game may be. I never thought I would again be doing the things I am now, and feel like I am back in my game—thank you, Virginia Spine Institute.

Michael W. Hasz, M.D., F.A.C.S.

Dr. Hasz is a spine surgeon at the Virginia Spine Institute. He is board certified by The American Board of Spine Surgery, a Fellow in the American Academy of Orthopaedic Surgeons and a member of both the American Association of Orthopaedic Surgeons and the North American Spine Society. He was Chairman of the Department of Orthopaedic Surgery and Director of Spinal Surgery at the Andrews Air Force Base/Malcolm Grow Medical Center in Maryland. He currently holds an appointment as Clinical Instructor of Orthopaedic Surgery and Assistant Professor of Surgery at the Uniformed Services Health Science University in Bethesda, Maryland.

Patient Advocacy
Insurance Denials Are on the Rise!

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

"I pay a lot for my insurance! Why won't they cover the treatment I need?"

Doctors are hearing this statement from frustrated patients more and more every day, and it is getting in the way of our ability to take care of people.

There has been a noticeable increase in the rate of insurance denials over the past two years, and it seems that every day insurers are adding more treatments and tests to their list of denied or non-covered services. On many occasions, insurance companies justify their denials by claiming they are "looking out for the best interest of their customers" or "protecting" their clients from "experimental" treatment. This is misleading because many insurance denials do not have anything to do with improving patient care, and their actual intent is to save money by rationing or delaying what care is delivered.

In some cases, increasing regulations and denials are simply an inconvenience to patients and health care practitioners who are trying to help them. However, there are many times when these denials truly jeopardize patients' lives. There are an increasing number of patients in America who are denied life saving medications and surgical interventions for financial reasons.

The increasing denial rate for claims has taken place for several reasons. Some common reasons for denial include incomplete or inaccurate insurance information, lack of precertification, diagnosis or procedure code errors, and insufficient medical necessity.

For patients and doctors who are trying to deal with these claim denials, it is important to try to identify why a claim was denied and try to meet all the insurance company criteria for treatment. In many cases, multiple applications or reapplications are required. It is also important to keep detailed records of this process, and in some cases, it becomes necessary to enlist the help of other specialists, doctors, and hospitals. Other health advocates may even play a role.

It has gotten to the point where I talk with patients about the likelihood of an insurance denial on the very day when we decide to schedule a surgical procedure. Patients need to know how the system works and be prepared for the increasing number of bumps along the road. This is particularly important given that many final insurance coverage decisions (denials) seem to happen just prior to the proposed treatment (the night before surgery); this timing is particularly stressful and inconvenient for patients.

It is troubling that there has been such a major change in coverage practices recently. Many treatments that have previously been covered are now being reclassified as non-covered services. Yes, that means treatments that a policy has covered for years are now being denied without any medical reason. In my opinion, it does not make sense for a company to suddenly consider a treatment that they have always covered as "experimental." It was not considered experimental previously, and in many cases these changes are simply another way to deny care and save money.

A major concern is the recent re-definition of the term "experimental". The process of getting Food and Drug Administration (FDA) approval for a medicine is highly time consuming, very expensive, and takes years. In the past, once a medication or treatment was FDA approved for one indication, doctors could use that medication in other appropriate ways depending on what was best for a patient.

Imagine a study that showed a medicine was safe and effective for treating blood pressure, and the study had chosen to include patients who were 40 to 50 years of age. Once the medicine was FDA approved, doctors could choose to use that medicine for a patient who

C. Good/Journal of the Spinal Research Foundation 9 (2014) 28–30

was 51 years old, even though the FDA approval study only included 40 to 50 year olds. This was good medical care.

The recent trend is to strictly apply the FDA study criteria and only approve treatments within that very narrow group. In the new scenario, an insurance company can choose to pay for the medicine only in the 40 to 50 year old patients and consider the medicine "experimental" for anyone older or younger. This allows companies and the government to save money, but denies good medical care to many people. It is impossible for a drug company to do an expensive FDA approval study for every possible patient or condition that for which a treatment may be used.

Another important concept is of the idea of "medical necessity." In many cases, insurance companies or payers will deny care, stating that a medication or procedure is not medically necessary. There have been a number of class action settlements in recent years debating the definition of the term medically necessary. The most patient-centered definition would refer to any treatment that is needed for a particular patient in a particular set of circumstances. Unfortunately, the much more commonly occurring scenario is that an insurance policy creates a list with a number of treatments which are NEVER considered "medically necessary" and therefore not covered under any circumstances.

One additional problem is that there is not a lot of transparency in the decision-making. In many cases, doctors cannot even respond to denials because no one knows where the denials are coming from and who made the final decisions; it seems the carriers do not believe that patient or physician input is warranted in these treatment decisions. Another issue is that the actual decision makers at the insurance company level are protected from being contacted. I have been a part of many discussions fighting for a patient's care where the insurance company doctor will actually tell me that they do not have the power to change the denial whether they agree that it is in the best interest medically for the patient or not. If this doctor has no authority, then why can't I speak with the person who does?

The preauthorization process for any treatment has become much more rigorous for patients and physicians in the past few years. This takes physicians away from their patients and forces them to spend time debating clinical guidelines and treatment decisions. This level of discussion and debate is routinely being required for every test or treatment that a physician may recommend for a patient. If your doctor orders you two tests and one treatment, then he or she is probably required to make at least three time-consuming phone calls just to get those things approved.

These peer-to-peer debates only take place during office hours and are very commonly scheduled at the convenience of the insurers. Basically, the insurance company will call at any time they find convenient without allowing the doctor to schedule a specific time. This pulls busy doctors out of their patients' rooms, delaying the office, and making all the patients wait. In this case, doctors have very little choice but to drop everything when they are called for fear that the treatments their patients so greatly need will be denied if they are unavailable. This has led to an increased wait time for patients in our office and an increasing level of patient frustration.

In the past, physicians could train their office staff, nurses, or physician assistants to discuss coverage issues with insurance companies. However, insurance companies now demand to speak only to the doctor, taking away from the time physicians can spend in face to face contact with their patients. This additional time spent on the phone with insurance companies costs doctors dearly, both in the relationship with their patients and financially because they are not reimbursed for their time spent addressing these issues. The more levels of appeals and denials, requiring more time on the phone, the more cost to the physician in terms of time and frustration, as well as financially. Many practices have had to hire additional staff members and pay for additional training just to manage appeals with the insurance company. Since it has become more difficult to fight this appeals process, many doctors have been forced to close their small or independent practices and join the large hospital group in order to share this new cost.

The increasing regulations have put a great stress on doctors and their staff and ultimately have decreased the amount of time that doctors spend actually treating patients. In my practice, I commonly meet patients who have been treated with physical therapy, pain management, injections, weight loss, acupuncture, exercise, and many other treatments over a period of many years. In most of these cases, these treatments have all been previously approved and paid for by the patient's insurance company. Although the insurance company has been involved in all the previous treatments as they were happening, new regulations are forcing doctors to go back and re-collect all of these previous records, sometimes over a period of many years, in order to document all of the previous failed treatments prior to approving any additional treatments moving forward. The insurance companies had already *approved* these treatments at the time and *paid* for them, yet are requiring doctors to spend incredible time to go back and organize old documentation before authorizing any further treatment.

In some cases, they are even requiring non-treating physicians to see the patient for a separate office visit to review records and concur that treatment is actually needed. They are looking to find things such as medical co-morbidities, psychiatric issues, financial issues, medication addictions, etc. In my practice, I had an insurance company require that a healthy patient with no history of mental illness see a psychiatrist to document that they were not depressed! At the time, I thought this was just a misunderstanding, but this scenario has become common place. Now, it is routine for a patient with absolutely no history of pain medicine use and no history of psychiatric illness to be required to see a psychiatrist or pain management physician before treatment will be approved. Not only is this a huge waste of the patient's and doctor's time, but this leads to an increased cost to the patient for the extra visits.

Insurance companies and the government are searching for ways to deny treatments in order to save their dollars and improve profitability. Denying service is the easiest cost-saving maneuver for insurance companies and for the government. Ultimately, this leads to a lack of access for appropriate treatments, which will greatly decrease the quality of life for millions of Americans.

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

Dr. Good is a spine surgeon at the Virginia Spine Institute. He has extensive training and experience in the treatment of complex spinal disorders with special expertise in non-operative and operative treatment of adult and pediatric spinal deformities including scoliosis, kyphosis, flatback, and spondylolisthesis. Dr. Good has co-authored numerous articles and has been invited to lecture nationally and internationally at the Scoliosis Research Society, the International Meeting on Advanced Spinal Techniques, the American Academy of Orthopaedic Surgeons, and the North American Spine Society.

From Your Personal Trainer
Core Exercises

Melissa Treat, R.N., B.S., C.P.T.

A healthy spine is an essential aspect of a happy, healthy, pain-free life. Spinal health is a culmination of one's core strength, stability, mobility, and alignment. Core strength has recently become a bit of a buzz word in the fitness industry, but what exactly is the core, and how can you strengthen it? Unfortunately, core strengthening is not as easy as cranking out a bunch of crunches in an effort to get that six-pack ready for the summertime. It is important to visualize the human body as a three-dimension functional unit, as each part of our kinetic chain affects the rest of our body. The spine and the numerous muscles that support it are essential for our posture, balance, and functional strength. The core is essentially made up of the deep intrinsic abdominal muscles, the muscles along the spine, or the spinal erectors, the muscles of the pelvis and the gluteal (buttock) muscles.

Think of the muscles of your trunk and spine as being analogous to the supporting wires of a sailboat mast. If the mast does not have adequately strong supporting wires, it will be weak, flimsy, and the entire structure will be unable to withstand the forces of the wind in the sails. The muscles that surround the spinal column serve a similar purpose in core strength and spinal health. The muscles of your core help balance the spine during normal daily activities and exercise and prevent the weight of your body from being carried by the spine in a harmful way. The stronger and better conditioned these muscles are, the more support there is for your spine, which results in better distribution of the loads that your spine must carry during daily life.

To take this analogy a step further, imagine if the wires on the front of the sailboat mast were set tighter than the back. The mast would be pulled forward, changing the entire structure and causing weakness and vulnerability to damage and breakage. Now, apply this scenario to your body. Many times back pain is caused by an imbalance in strength and alignment of the fronts of our bodies, or the anterior kinetic chain, and the backs of our bodies, the posterior kinetic chain.

In our modern society, there are two primary causes of this type of imbalance. The first cause is a sedentary lifestyle, including long periods of sitting at a desk, hunching forward to see a computer, driving in a car and leaning forward into the steering wheel, and even cumulative time looking down at a cell phone or tablet. This type of repetitive internally rotated posturing teaches the muscles of our anterior chain (the front of the neck, the chest, abdominal wall, and hip flexors) to constantly be in a shortened, tight, and limited range of motion. When the anterior chain is consistently tight, the posterior chain (the other side of our sailboat mast) will be lengthened and weakened, leading to a neuromuscular imbalance, or the inability of the brain to properly send signals to the important muscles that support our spine. The other common cause of such an imbalance is overtraining the abdominal wall and hip flexors, as can be seen in repetitive forward-motion athletes (such as runners and bikers) and the six-pack-hungry, 200-crunches-a-day enthusiasts. Overtraining one side of our body, in one plane of motion, places great stress on our spine and makes us vulnerable to weakness, pain, and spinal injury.

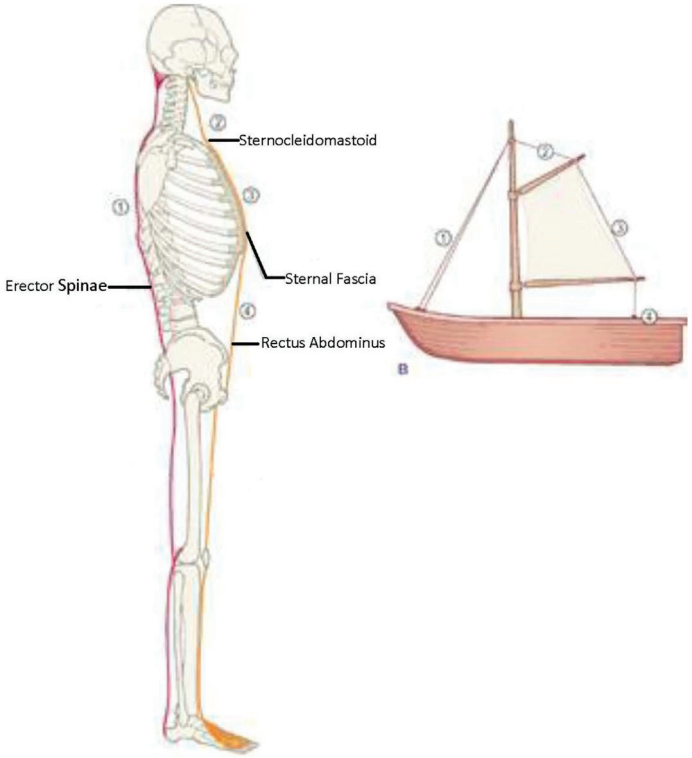


Image courtesy of anatomytrains.com

Now that you understand the importance of core strength, alignment, mobility, and stability to maintaining good spinal health, let's introduce a few of the best exercises to strengthen your core. This series of exercises will cover the basics and progress in level of difficulty. These exercises work on the mobility of the lumbar spine and pelvis, the ability of the deepest layer of the abdominal muscles, the transverse abdominals, to stabilize the spine, the flexibility of the hamstrings and lumbo-pelvic hip complex, and the strength and neuromuscular coordination between all of the muscles of our core.

Exercise 1: Cats and Dogs

Cat: Start on all fours. On an exhalation, round your back by pulling your belly button toward the ceiling and simultaneously tucking your chin toward your chest. On an inhalation, move through the starting position to the opposite spinal position, or Dog.

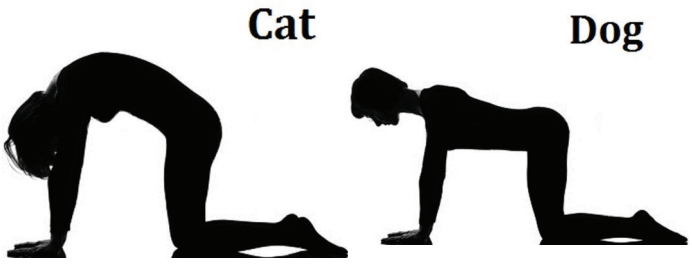


Image courtesy of healinglifestyles.com.

Dog: Create an arch in your spine by reaching your belly button toward the ground, while gently raising your chin toward the ceiling.

Exercise 2: Bird Dogs

Start with your hands under your shoulders and knees under your hips, while keeping your head, neck, and back straight. Raise your right arm and reach it forward until it is in line with your torso. As you bring your arm forward, kick your left leg backwards until it is straight and in line with your torso; hold for one second. Slowly bring your arm and leg back to the ground and repeat with the opposite arm and leg.

Image courtesy of builtlean.com.

Exercise 3: Dead Bugs

Lie flat on your back with your knees in the air above your hips and your feet straight out. Lift your hands in the air above your chest and hold them straight. You will be working your opposite arm and leg each time. Begin by lowering your left arm back behind your head, keeping your elbow straight, while extending your right leg straight out and lowering it to the floor, until it is parallel to the floor. Pull your leg and arm back to the original position and repeat with the opposite arm and leg combination. Remember to inhale as you extend the arm and leg and exhale as you bring them back to the starting position.

Image courtesy of in2town.co.uk.

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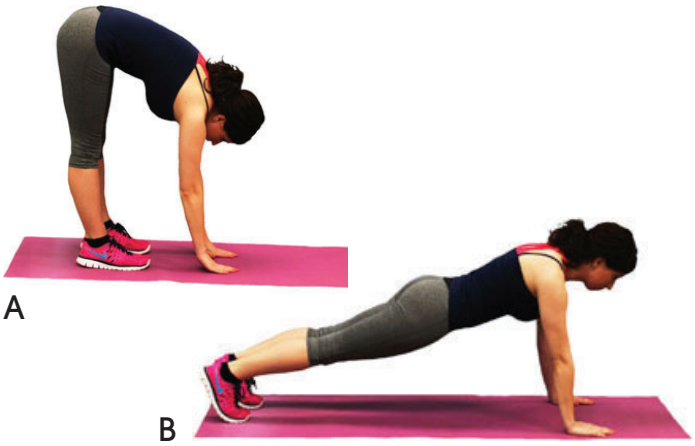
Exercise 4: Single Leg Hip Raises

Lie face-up on the floor with your left knee bent and your right leg straight. Raise your right leg until it is in line with your left thigh. Push your hips upward, keeping your left leg elevated. Pause, then slowly lower your body and leg back to the starting position. Complete 15 repetitions with your left leg, then switch legs and repeat with your right leg.

Exercise 5: Inchworms

From a standing position, place your hands on the ground (bend your knees if needed). Walk your hands forward until they are under your shoulders in a high plank position. Keeping your knees straight, take small steps forward, bringing your feet into your hands (returning to position A). Repeat 10 times.



Exercise 6: World's Greatest Stretch

From a plank position, bend the right knee to bring the right foot to the outside of the right hand. Keep bending the right knee while relaxing the hips toward the ground as you reach the right hand to the ceiling, rotating the gaze to look up toward the ceiling. Return to starting position and repeat on the left side. Perform 5 reps on each side.

Exercise 7: Balance and Reach

With a slight bend in the left knee, start by balancing on the left foot. Keeping the chest forward and the back flat, hinge from the hips, reaching the right hand towards the left foot. Focus on balance by pulling the belly button into the spine and engaging all muscles from the bottom of the left foot up through the left hamstring and gluteal muscles. Do not round the spine at all. Complete the motion by standing all the way up, fully extending the hip. Complete 12 repetitions on left side, trying to keep the right foot off the ground. Switch sides and repeat.

Exercise 8: Single Leg Stand Ups

Start in a seated position on a bench (the higher the bench, the easier the exercise will be). Extend the right leg out in front of you. Keeping the left foot planted on the ground, stand up on the left foot (if unable to perform the exercise this way, the right heel can be placed gently on the ground as a "crutch" to help standing up). Repeat 10 to 12 repetitions on the left leg, and then switch to the right leg.

Exercise 9: Plank Progressions

The planks on the left side of this image are for beginners. With knees on the floor, maintain a neutral spine as you stabilize on either the hands (easiest option in terms of core strength, slightly harder in terms of arm strength) or the elbows. Hold for 30 to 60 seconds, making sure to keep your belly button pulled to the spine with no arch in the lower back. The more challenging options are on the right. Keep your shoulders directly over either the hands or the elbows, belly button pulled to spine, gluteal muscles, quadriceps, and hamstrings engaged throughout.

Image courtesy of Campus Recreation Services, University of Maryland.

Hold for 30 to 60 seconds, complete 3 to 5 sets. If your back is hurting during this exercise, you are not doing it properly! Abdominal engagement without letting the hips drop or the spine sag is the focus for all types of planks.

Melissa Treat, R.N., B.S., C.P.T.

Melissa Treat has been in the fitness industry for 6 years, working as a personal trainer and group fitness instructor at Tyson's Sport and Health in McLean, VA. She has a degree in Kinesiology from University of Maryland and is certified with ACE, NASM Corrective Exercise, Crossfit Level One, Crossfit Mobility, and TRX Suspension Training. She works with her clients on total health and wellness, overall fitness, disease and injury prevention, mobility and flexibility, total body restoration, performance enhancement, and rehabilitation from various injuries and surgeries. She is passionate for health and fitness and enjoys helping people bring exercise and nutrition into their lives.

Technological Advancements in Spinal Fusion Implants: A Summary of the Current Scientific and Clinical Research on Titanium Engineered Surfaces

Paul J. Slosar, Jr., M.D.

Background

Lumbar interbody fusion is commonly performed by inserting an implant into the disc space. Interbody fusions are beneficial because they result in high fusion rates, maintain spinal alignment, and allow for indirect decompression of the neuroforamen.[1] Currently, the two most commonly used implants are made of polyether ether ketone (PEEK) or allograft bone. Threaded titanium (Ti) cages were used in the past, but many surgeons became concerned about challenges with imaging the fusion around titanium as well as subsidence, and their use declined. These implants were previously used as threaded "stand-alone" constructs (no pedicle screw fixation). This was shown to be mechanically inferior and led to more clinical failures due to surgical technique rather than the implant material.

A new class of Ti implants with nano-roughened (micron-level) surface modifications have been shown to induce greater osteoblast differentiation of culture stem cells than PEEK.[2] There is an emerging trend in spine surgery to move away from plastic interbody fusion spacers. This trend has stimulated an expanding clinical and scientific interest in the surface technology of acid-etched titanium spinal implants. The purpose of this article is to review the scientific literature surrounding these unique titanium engineered surfaces and discuss the clinical outcomes to date.

Titanium alloys have been extensively studied in the dental literature and have a well-established history of use. Basic science studies have shown that titanium, especially with roughened nano-surface (micron-level) properties, creates a favorable bone-implant contact surface and superior osseointegration with the surrounding bone.[3,4,5] In vitro experiments comparing the responses of immature osteoblasts to roughened and smooth titanium surfaces conclude that the differentiation of the cells is greater when the surface has an engineered texture with micron-scale (10^{-9}) roughness. This is the scale on which the mesenchymal stem cells are stimulated.

Dual acid etching processes applied to the surface of Ti has been shown to stimulate local, physiologic bone morphogenetic protein (BMP) production, transforming growth factor beta (TGF-β), and vascular endothelial growth factor (VEGF), all of which promote a natural osteogenic environment and may facilitate bone integration with the implant surface.[3,4] This is a novel concept that has not been previously examined in the spinal fusion clinical application.

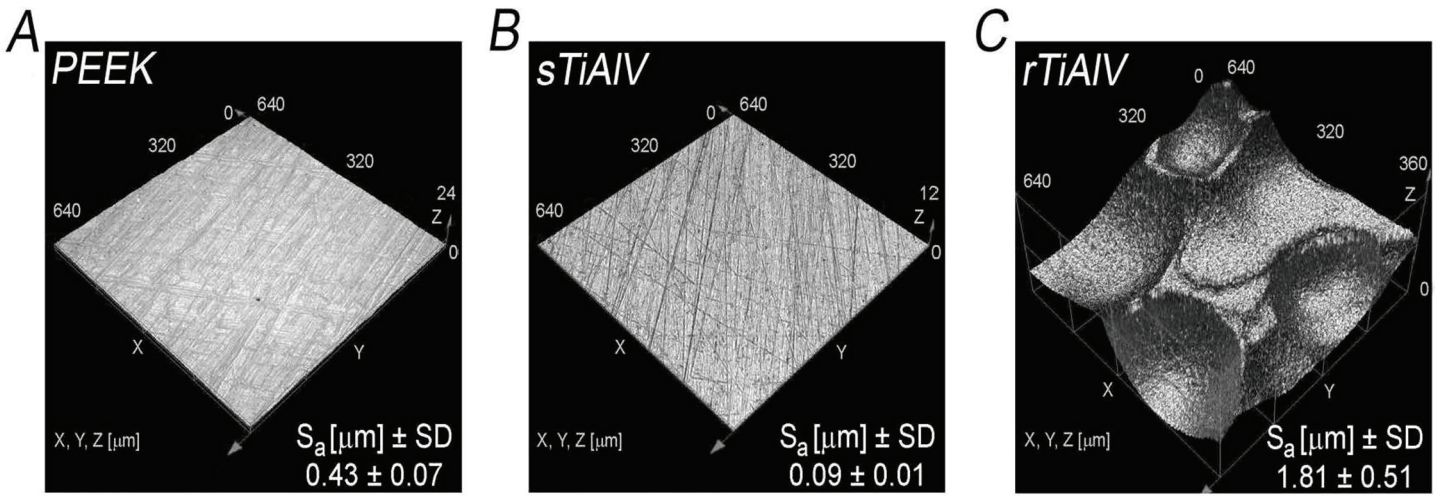


Figure 1. Laser Microscopy Images and Average-Roughness (Sa) Values of PEEK (A), sTiAlV/ Smooth Titanium (B), and rTiAlV/Roughened Titanium (C) Surfaces of 644 × 644 Micron Field.

Basic Science

The scientific evidence supporting the physiologic benefits of acid-etched titanium is strong. Gittens et al. published a paper in 2013 which demonstrated human mesenchymal stem cells reacted favorably to nano-texturing (10^{-9} level) the surface of titanium.[6] The cell cultures preferentially expressed strong osteoblastic differentiation as well as increased levels of VEGF. Furthermore, Olivares-Navarrete and co-authors reported their data in two published studies. They compared nano-texutured Ti to PEEK and found that the Ti showed significant upregulation in factors associated with bone formation and angiogenesis, both critical for successful fusion. PEEK and smooth Ti both demonstrated inferior results.[3] In their other paper, Olivares-Navarrete et al. demonstrated statistically significant upregulation of BMP-2, BMP-4 and BMP-7, with nano-textured Ti.[2] The PEEK results showed no upregulation of these important bone-forming factors. Summarizing these studies, it is clear that modifying the surface structure to a micron/nano-level can create an osteogenic environment in the host bone. This may enhance bone formation and implant stability, fostering bone ingrowth without exogenous growth factors.

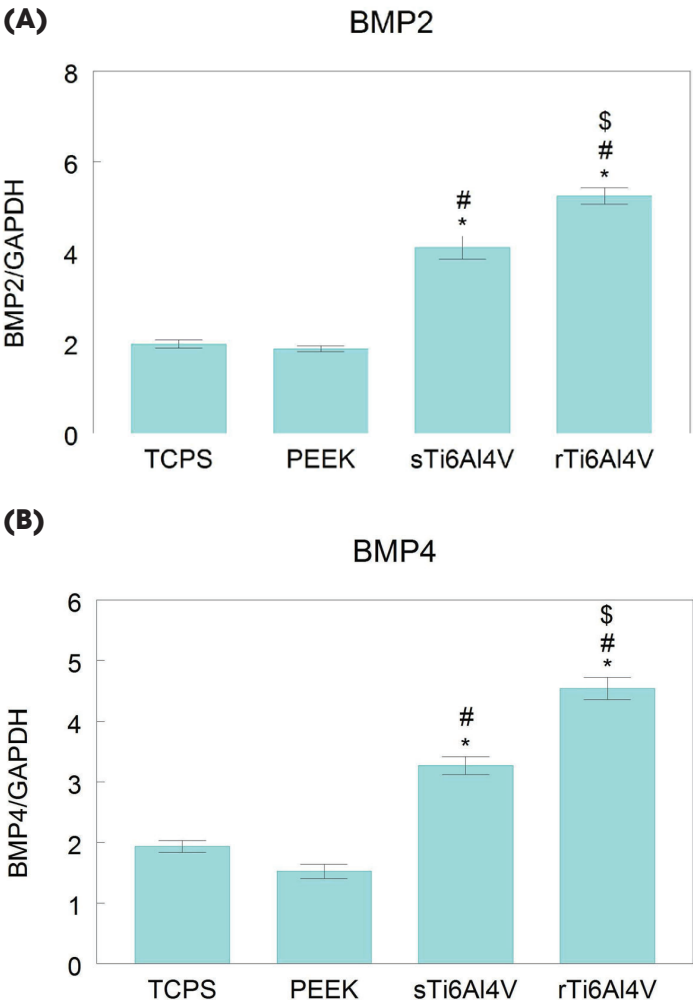


Figure 2. (A) Mesenchymal Stem Cells were harvested 12 hours after confluence on TCPS. Levels of mRNA for BMP2, BMP4 were measured by real-time qPCR and normalized to GAPDH. *p<0.05, v. TCPS; #p<0.05, v. PEEK; $p<0.05, v. sTiAlV (B) Mesenchymal Stem Cells were harvested 12 hours after confluence on TCPS. Levels of mRNA for BMP2, BMP4 were measured by real-time qPCR and normalized to GAPDH. *p<0.05, v. TCPS; #p<0.05, v. PEEK; $p<0.05, v. sTiAlV.

Clinical Applications

Titanium is the most commonly implanted medical material. It is the standard implant material of choice for trauma plates and screws, total joint implants, pedicle screws, among others. It is biocompatible and MRI compatible.

Dental surgeons and total joint surgeons have long been interested in the surface technology of their implants in order to drive osseous integration.[5,7] This is a relatively new but exciting area of increased focus in spine surgery. Acid-etched Ti pedicle screws have shown superior pull-out strength compared to standard screws due to improved bone-screw integration.[4]

PEEK (polyether ether ketone) is a polymer plastic material that has been used commonly by spine surgeons as an option for interbody fusions. This material has no intrinsic capacity to bond to bone and does not elicit a favorable response in the host bone. Therefore, a strong biologic catalyst chemical such as bone morphogenetic protein (BMP) is commonly used to create a fusion with PEEK. BMP, however, has been associated with some concerning complications such as ectopic bone growth and nerve inflammation.[8] It is

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also expensive compared to alternative biologic bone graft extenders, so its use is being restricted by many hospitals and insurance carriers.

Titanium with micron (nano) scale surface treatments is gaining substantial ground with spine surgeons looking to move away from PEEK or strongly inflammatory biologics. Titan Spine, LLC, (Mequon, WI) is the only company that manufactures titanium fusion implants with this proprietary surface technology.

Figure 3. Roughened Surface Titanium Implants used for Interbody Spinal Fusions

Clinical Investigations

In 2013, Dr. Girasole and his co-authors published a retrospective review of 82 patients who underwent transforaminal lumbar interbody fusions (TLIF) using a Titan Endoskeleton implant.[9] All patients had local bone graft plus an allograft bone extender (Osteo-Sponge®; Bacterin International, Belgrade, Montana). Patients were divided into two cohorts with one studied at 6 months and the other at 12 months after surgery.

Fine-cut CT scans were reviewed by an independent radiologist, and fusion results were calculated using a grading scale. At 6 months, the fusion rate was 93.2%; at 12 months, the fusion rate was 97.4%. There were no surgical complications and no device-related complications. The authors compared their results with many other published articles and concluded that their results compared equally well.

Our institution, SpineCare Medical Group, has presented data on two clinical investigations looking at the results of anterior lumbar interbody fusions (ALIF) using the Titan Endoskeleton TA® implant.

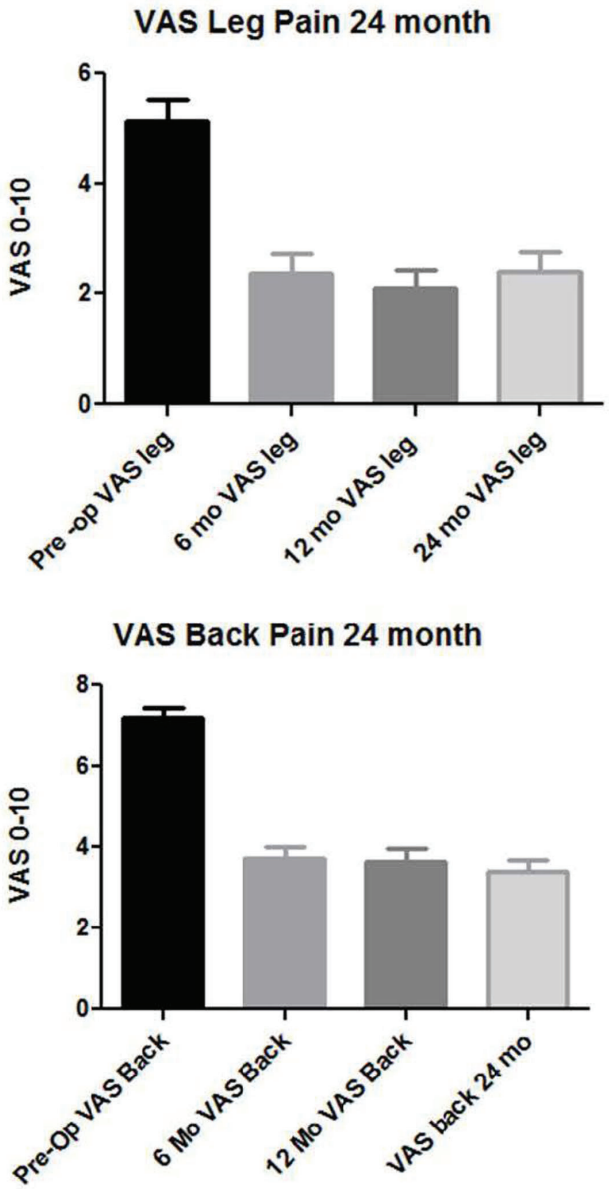

Figure 4. Clinical Outcomes of Anterior Lumbar Interbody Fusions. Visual Analog Scale (VAS): 0 = no pain; 10 = worst pain imaginable.

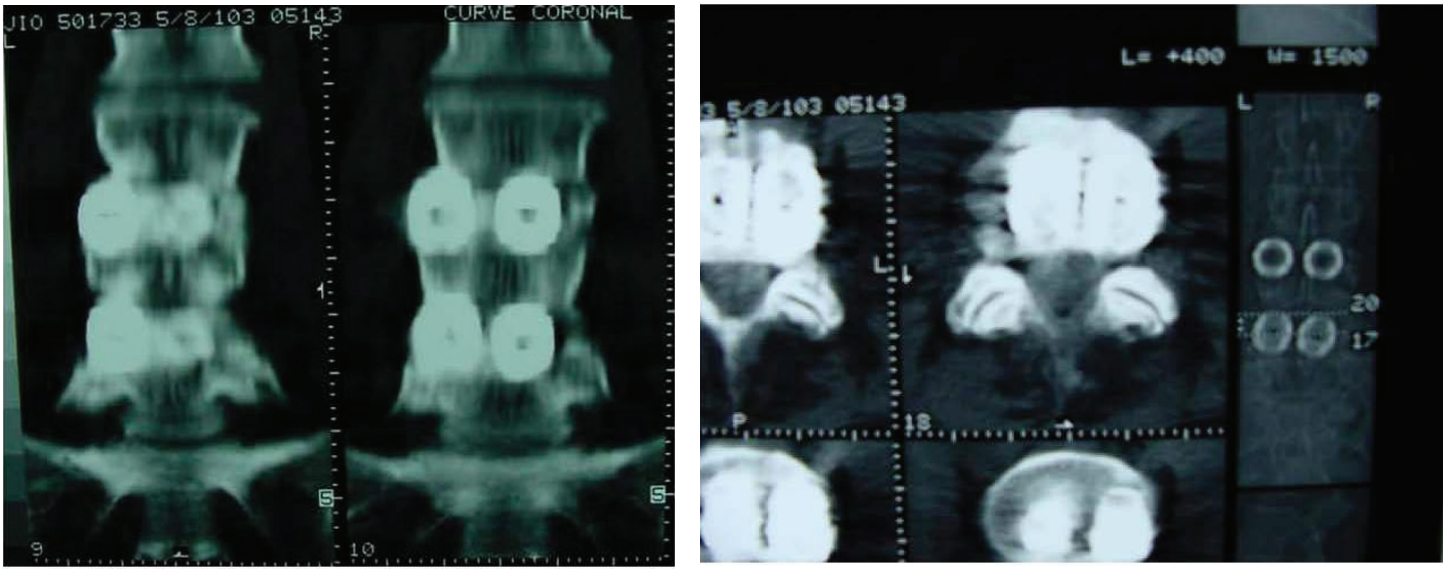

Figure 5. CT Scan of Older Titanium Fusion Cage Technology.

The first is a clinical outcomes study of 77 patients enrolled prospectively with 24 month post-operative follow up results.[10] All patients underwent ALIF with a standard dose (3 mg/fusion level) of Infuse® (Medtronic, Inc.) as the biologic bone graft substitute. Pedicle screw fixation was used in 94% of the cases with 6% having a stand-alone ALIF. Clinical outcomes (Oswestry Disability Index: ODI; Visual Numerical Scale: VNS 0-10) were measured at 6, 12, and 24 months.

One of the most compelling results was that the functional improvement was rapidly noticed by the patients by 6 months, and these results held without decline at both 12 and 24 months. Meaningful clinical improvements, ODI $>$ 15 points and VNS $>$ 3 points, were noted in the majority of the patients. There were no device related complications.

Another area of key interest to surgeons considering using titanium interbody devices is radiographic fusion assessment. Many express concerns about the

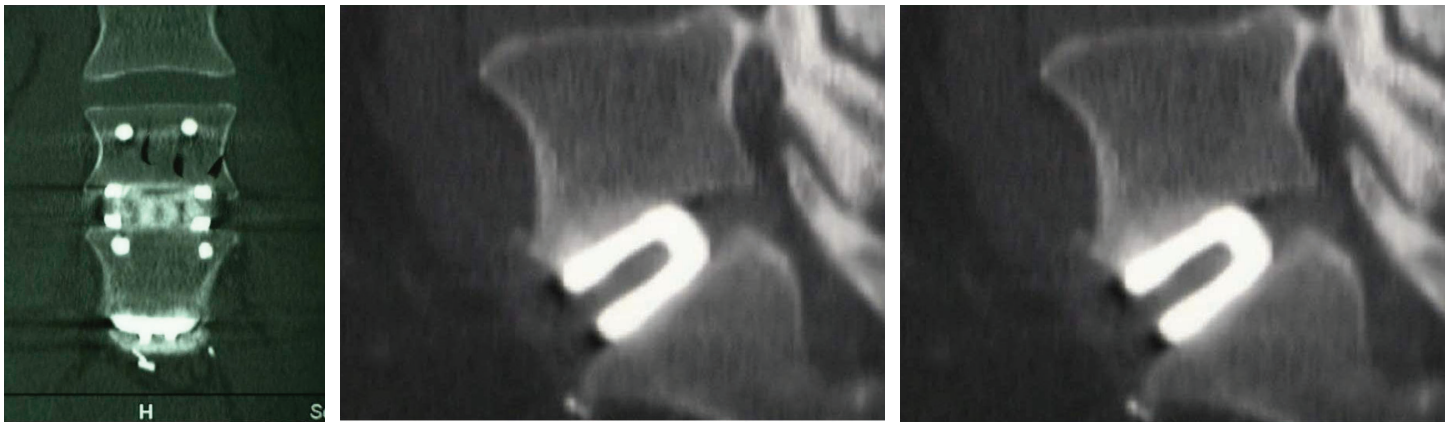

Figure 6a. CT Scan Images.

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Reviewer	Grade 5	Grade 4	Grade 3	Grade 2	Grade 1
A	45 (80%)	8 (14%)	2 (4%)	1 (2%)	0 (0%)
B	51 (91%)	5 (9%)	0 (0%)	0 (0%)	0 (0%)
Agreement					
Same Grade	**0.77**				
Within 1 Grade	**0.95**				

Figure 7. Overall Fusion Grades: Grade 5: Definitely Fused; Grade 4: Probably Fused; Grade 3: Indeterminate; Grade 2: Probably Not Fused; Grade 1: Definitely Not Fused.

accuracy of CT scans due to problems of scatter and artifact. Previously published reports on this issue have generally focused on older technologies using paired, threaded, smooth titanium devices.[11–14] These devices had smaller apertures for bone graft and a much greater problem with artifact.

My co-authors and I decided to investigate the interobserver reliability of CT scans in assessing fusion criteria in ALIF patients with these new titanium interbody implants (Titan Spine, LLC).[15] Thirty-three patients (56 spinal fusion segments) underwent random CT scans as part of the protocol for the clinical outcomes study discussed above. Scans were performed at 6, 9, and 12 months to look for any variability in fusion rates at different times. The images were sent to two independent radiologists blinded to outcomes to assess for fusion variables.

The interobserver agreement for the overall study was 88% (agreement on 345/394 data points). No difference was noted between patient CT results among the patients studied at 6, 9, or 12 months. Interobserver reliability for fusion formation was 77% agreement between the radiologists. Overall fusion rates were 94%. In conclusion, the titanium implant studied demonstrated minimal artifact, minimal subsidence, and easily visualized trabecular bone. The investigators concluded that radiographic fusion criteria can be reliably assessed using CT scans with a high degree of interobserver agreement.

Success Story of a Spinal Champion

The Spinal Research Foundation is focused on patient care, advocacy, and promoting scientific research to improve the outcomes of spinal care. It is always very special for the surgeons and our staff to see patients directly benefit from these scientific advancements. An example of such a patient is RR.

RR was a competitive adult athlete, doing triathlons and endurance events until he injured his back. As a teacher and parent, RR found that he couldn't even play with the kids at home or on the playground at school. He struggled for over a year with debilitating back pain and nerve pain into his leg. After his evaluation, I diagnosed him with spinal in-

Figure 8. Spinal Champion RR and Dr. Slosar shake hands after the SRF *We've Got Your Back* Race hosted by SpineCare Medical Group in September 2013.

Figure 9. RR crossing the finish line of the *We've Got Your Back* Race, celebrating his success of overcoming his debilitating back pain just five months after spinal surgery.

stability (spondylolisthesis) as well as a separate disc herniation injury at the next level. My recommendation was fusion of both discs with the Titan interbody implants.

Within five days after surgery, RR was up and able to move the way patients do when they are closer to four weeks after an operation. He entered a walking race at 3 months after surgery, but RR couldn't resist and ran it without pain, never looking back. He later participated in the 2013 San Francisco *We've Got Your Back* Race that benefits the Spinal Research Foundation and ran 4.2 miles without a problem (5 months post-op), finishing 1st in his age group.

RR is a Spinal Champion: an inspiration to his doctors, his family, and his friends.

Conclusion

Over the past eight years, there have been significant scientific advancements with acid-etched titanium (nano-textured) spinal implants. Most importantly, the remarkable basic science data generated in the laboratory is carrying over into the surgical and clinical side of care. Advances in surgical techniques and implants benefit patients when applied carefully and accurately. The clinical results outlined in this review paper are very encouraging, offering us and our patients a step forward; closer to achieving successful outcomes for even more of our patients in the future.

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Dr. Slosar is an orthopedic spine surgeon and President of SpineCare Medical Group in Daly City, CA. He is also the Medical Director of the Spine Care Institute of San Francisco, Co-Director of the San Francisco Spine Institute Surgical Fellowship training program, and Director of Surgical Research. He has authored over 20 original articles in peer-reviewed journals and several book chapters, serves as an editorial board member for multiple medical journals, and has given numerous podium presentations at national and international meetings. Dr. Slosar is a member of the The International Society for the Study of Lumbar Spine, the American Academy of Orthopaedic Surgery, the North American Spine Society, and additional local and state medical societies. His current research interests include minimally invasive surgical techniques, spinal motion-preservation technology, and implant surface technologies.

Use of Antibiotics to Treat Low Back Pain

Michael W. Hasz, M.D., F.A.C.S.

Dr. Michael Hasz is heading a study to evaluate the use of antibiotics in low back pain, specifically to determine the possible incidence of infection as a cause of low back pain in surgical patients.

Two recent studies published in the European Spine Journal in April 2013 suggest that antibiotics may be considered as a treatment option for patients with chronic low back pain. However, the authors from the University of Southern Denmark do note the treatment of low back pain with antibiotics should be considered with some caution.[1,2]

The first study published by researchers at the University of Denmark was designed to test the incidence of infection in patients with disc herniations. Specifically, in this first study, cultures from the herniated disc were obtained at the time of surgery in patients whose MRI revealed bone edema with Modic I changes adjacent to the disc herniation. Nuclear tissue examined from herniated discs demonstrated the incidence of positive disc cultures in nearly half, 46%, of patients. These patients had not undergone any previous surgery nor had any injections, yet, anaerobic cultures were positive in approximately 43% of them and 7% had dual infections of both aerobic and anaerobic cultures.

This study was performed due to previous studies demonstrating a presence of a low virulent anaerobic microorganism called *Propionibacterium acmes* in 7% to 53% of patients.

This study suggests that edema to bones adjacent to a disc herniation identified on MRI may be due to an infection rather than to mechanical changes or increased stress caused by an incompetent disc.

In a second study from the University of Denmark, also in April 2013, patients with chronic low back pain with the same Modic I bone edema changes identified on MRI, were treated with antibiotics for 100 days. Antibiotic treatment for the 100 days was Bioclavid* versus placebo.

One-hundred forty-four of the 162 original patients were evaluated one year after the study, and the antibiotic group had statistically significant improvement in all outcomes measured from the time the antibiotics were completed at 100 days until the follow-up at one year.

To further evaluate the possible role of infection in patients with chronic low back pain severe enough to require surgery, my staff and I at the Virginia Spine Institute (VSI) are currently sending the discs that are removed during surgery off for culture. It should be noted that this study excludes patients with known severe infections and is being performed in the population of patients with back pain similar to patients in the previous studies noted.

Up to this point, over twenty discs from VSI patients who underwent surgery for their severe back pain have been tested. Thus far, no disc cultures have grown any bacteria, either aerobic or anaerobic in nature. Based upon the first Danish study, we were expecting to find a positive culture in nearly half of our patients. However, no growth has been seen in any culture.

Currently, we are continuing to analyze the discs in samples of patients with ongoing severe back pain. We feel that harvesting the entire disc and sending it for culture has the best opportunity for infections to be identified. Additionally, at some point we may be able to determine which patients could fit criteria such as in the Danish study. However, at this time, based on the absence of infection in patients with back pain, we are currently not recommending long-term antibiotic treatment for these patients.

*Bioclavid is amoxicillin with clavulanate, clavulanic acid.

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Dr. Hasz is a spine surgeon at the Virginia Spine Institute. He is board certified by The American Board of Spine Surgery, a Fellow in the American Academy of Orthopaedic Surgeons and a member of both the American Association of Orthopaedic Surgeons and the North American Spine Society. He was Chairman of the Department of Orthopaedic Surgery and Director of Spinal Surgery at the Andrews Air Force Base/Malcolm Grow Medical Center in Maryland. He currently holds an appointment as Clinical Instructor of Orthopaedic Surgery and Assistant Professor of Surgery at the Uniformed Services Health Science University in Bethesda, Maryland.

Vitamin D Deficiency

Michael W. Hasz, M.D., F.A.C.S.

Vitamin D is a nutrient which is essential for good bone health, collagen healing, as well as aiding in many biochemical processes which help promote health and avoid diseases, particularly cancer and cardiovascular disease. It actually has the structure of a hormone and has many of the physiologic effects of a hormone. Vitamin D is obtained through exposure to the sun, the skin being able to manufacture vitamin D with exposure to the UVB rays of sunlight. Vitamin D can also be obtained through the diet.

Vitamin D has been reported to be deficient in many populations, particularly in groups of people who do not get adequate sunlight or have low exposure in their geographical locations. Indeed, people who live north of the equivalent of Atlanta, Georgia often have low vitamin D.

There have been multiple studies that have identified low levels of Vitamin D in the US population. Binkly and Ramurthy (2012) reported that approximately three-quarters of all adults in the United States have low levels of Vitamin D. Low levels were defined in their study as less than 30–32 nanograms per milliliter of blood (ng/mL). Christina Arnold (2010) reported that vitamin D is required for immune function, as receptors for vitamin D are identified on T and B white blood cells. Vitamin D also aids in the prevention of diabetes as well as the reduction of cardiovascular disease. Arnold also cited various studies suggesting a range between 24% to greater than 50% of patients have low vitamin D levels.

The preliminary information coming from a review of my current patients at the Virginia Spine Institute has demonstrated in a sample size of approximately 150 patients that more than 50% have low vitamin D levels, low being defined as less than 30 ng/mL. Many authors suggest that an optimal vitamin D level should be greater than 50 or 60 ng/mL, and using these criteria, only 10% of the Virginia Spine Institute patient sample is in this range.

Having between 50% and 90% of patients with low or less than optimal vitamin D levels would suggest an epidemic. Given the multiple roles that vitamin D plays in overall health, supplementation, dietary changes, and other interventions should be performed in order to increase the vitamin D levels in the population.

Table 1. Reference Ranges for 25 OH Vitamin D.[3]

Level	Clinical
<10 ng/mL	Severe deficiency*
10-25 ng/mL	Mild to moderate 25 OH D deficiency**
25-80 ng/mL	Optimum 25 OH D level***
80 ng/mL	Toxicity possible****

*Could be associated with osteomalacia or rickets
**May be associated with increased risk of osteoporosis or secondary hyperparathyroidism
***Optimum levels in the normal population
****80 ng/mL is the lowest reported level associated with toxicity in patients without primary hyperparathyroidism and with normal renal function

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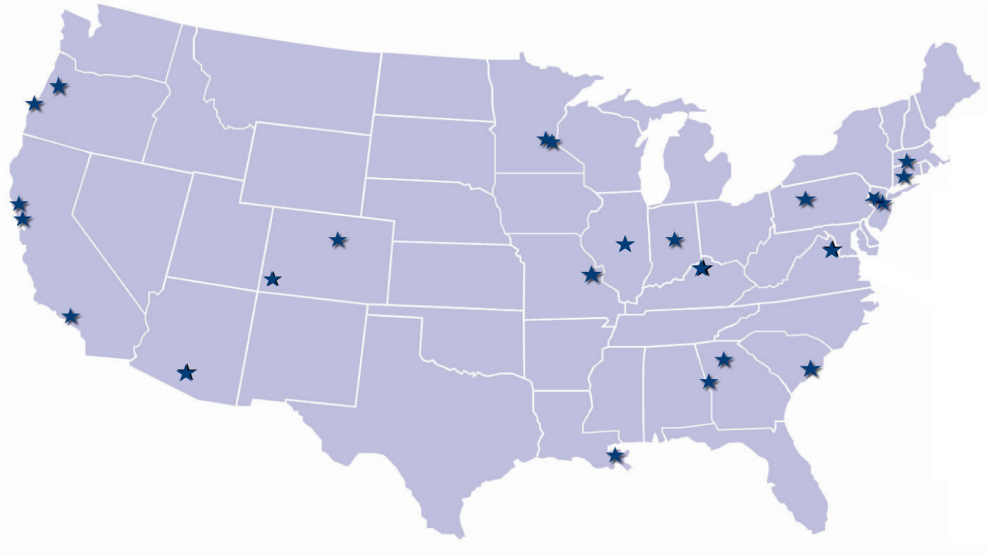
The Spinal Research Foundation has named 26 Research Partners across the country that share one core mission: improving spinal health care through research, education, and patient advocacy. These centers offer the best quality spinal health care while focusing on research programs designed to advance spinal treatments and techniques.



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Thank you,

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