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# EVIDENCE-BASED DECISION-MAKING FOR SPINAL HEALTHCARE

NATIONAL SPINE HEALTH FOUNDATION

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The National Spine Health Foundation is a nonprofit organization dedicated to improving spinal health care through patient education, advocacy and research. We educate everyone about the treatment and prevention of neck and back disorders, prove what works through patient reported outcomes research, and support patients on their journey to spinal health.

## EDITORIAL STAFF



**CONTACT**
National Spine Health Foundation
11800 Sunrise Valley Drive
Suite 330
Reston, VA 20191
Phone: (703) 766-5405
Email: info@spinehealth.org

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# Introduction

# LETTER FROM THE EDITOR

**Ehsan Jazini, MD**
*Editor-in-Chief*

## Evidence-Based Medicine in the Information Age

Instant access to information defines the current era of the Information Age. We have become accustomed to having endless information at our fingertips, which has allowed the patients of today to be much more knowledgeable about their conditions and treatment options than ever before. For many patients, it is no longer enough to take physicians at their word, but rather to seek knowledge from other sources, such as the Internet and through social media. A variety of content is now available to assist patients in making their healthcare decisions, from personal stories and experiences to data-driven outcomes from clinical research.

With the knowledgeable patient in mind, it has become imperative for all key stakeholders to have access to the latest evidence-based medicine to continue on the path of improving healthcare. The key stakeholders bearing the burden of the increasing cost of healthcare include: patients, clinicians, hospitals, insurance providers, and the government. We must work together to make progress.

The National Spine Health Foundation seeks to foster this knowledge and is on a mission to help educate spine patients through several unique programs such as Spine-Talks®, which captures experts in spinal health discussing current spine topics that interest patients the most. Another avenue in which the Foundation delivers current information to patients is this journal. It is the best, patient-centered journal comprised of articles from spinal experts from across the country on a wide variety of topics, such as the latest technology in spine surgery, non-surgical treatment options, and innovations in regenerative medicine.

The Foundation is dedicated to spinal research and has become a conduit for research over the past 20 years. We have had tremendous growth recently by working on extensive multi-centered robotic and augmented reality studies to demonstrate the efficacy of these minimally invasive surgical techniques. We also continue our work in demonstrating the benefits of enhanced surgical recovery programs and opioid-reducing pain management after spine surgery.

As Editor-In-Chief, these tremendous strides give me hope that we can continue to be leaders in evidence-based medicine. The path of translational medicine plays a huge role in the expansive advancements in spinal healthcare, both over the past decade and in the future. Proper patient education requires that leaders like the Foundation provide unbiased, relevant, and current information to patients which is guided by our Medical and Scientific Board of top spine experts. Together, we are excited to continue supporting the Foundation on its mission to provide unparalleled access to the answers spine patients seek in this day and age.

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# PRESIDENT'S NOTE

**Thomas C. Schuler, MD**
*President*

## Evidenced-Based Medicine: A Cautionary Tale

Evidence-based medicine is a term that has become ubiquitous in healthcare. The concept is that through analysis of clinical outcomes, one can identify the best way to treat a given medical condition. While the concept is exciting, findings are not generalizable to everyone and should not be used to make policy. Research allows us to critically analyze what has been done to determine what works, but the reality is that research is far from absolute. It gives us information on what may work for a given situation but is not a definitive answer.

In reality, the art of practicing medicine is complex and:

- Evolves over time
- Is based upon critical thinking
- Involves intellectual and technological innovation
- Involves the analysis of treatment outcomes to improve future treatments
- Requires physicians to evolve treatments as new knowledge and new technology become available

### INAPPROPRIATE INTERPRETATION DENIES ACCESS TO CARE

One significant but negative sequelae of evidence-based medicine is that medical insurance companies often use research findings as criteria to deny access to treatment for patients. While research is necessary to demonstrate and understand both positive and negative outcomes in medicine, the results are not meant to become a reason for insurance companies to deny access to care; but this is being done because insurance is a money-making business. This is most problematic for patients whose individual biology or response to treatment falls outside the generalized data that may become standardized as evidence-based medicine. Human beings and their physiology are not absolutes. We know that from DNA analysis, different people respond differently to medications and treatments. One person may metabolize medicine differently than another based upon their DNA; so regardless of what evidence-based data may show for the general public, it may not relate to each person and his or her response. This is especially true in surgical interventions and nonoperative treatments for spinal healthcare.

Another potential downside is the comparison of different treatments to develop evidence-based medicine. As inquisitive clinicians, we must ask ourselves, "has a correct comparison point been selected and how is that relevant for a given patient?" For example, when studying the incidence of spine surgery complications, it has been shown through research that patients over the age of 70 years have a much higher complication rate than those under 70. The reality is, if age 65 or 75 had been selected as the reference point in the study, the result would have been the same. At the end of the day, a researcher picks a data point and then makes comparisons to it, but that does not make it an absolute. A healthy 70 year old should

not be universally denied the treatments they need.

Another example is when studying the slippage of one vertebra on another (called spondylolisthesis) and when surgical intervention should be considered. During the study, the distance of slippage selected for comparison was 3 mm, a randomly selected number that was felt to be significant. The results of that study lead insurance companies to authorize surgery for spondylolisthesis only if the slippage is at least 3mm, but not less. This leaves many patients without access to treatment based on an arbitrary research data point. Ultimately, the patient needs surgery based on their failure to respond to non-surgical treatments and the amount of pain they are having, not on their millimeters of slippage. Maximizing profits was not the purpose of this research, yet evidence-based research is often misused by insurance companies to avoid paying for treatments.

Many innovations that benefit patients have not been proven through evidence-based medicine to the point that it satisfies insurance companies; therefore, these treatments are denied. Artificial disc studies have shown the technology to be extremely beneficial for patients having one- and two-level disc replacement surgeries. However, insurance companies deny coverage for three- and four-level disc replacements, or a combination of an artificial disc at one level and a fusion at another level, because the original FDA approval studies only looked at one- and two-levels. Either of these additional surgical options may be appropriate based on the patient's anatomy, but are completely denied by insurance companies. This is an inappropriate use of research data and incorrectly claims that since we have not proven something, it can never be done. If we take this position, medicine will never advance and patients will not have access to the best treatments that exist now or those that come in the future.

## INNOVATION AND CUSTOMIZATION

Evidence-based medicine is an attempt to prove what treatments work best for the general population. This is often done in *hindsight,* while innovation requires *foresight.* Innovation precedes evidence-based medicine, otherwise you could not try a new treatment if it was not proven. Anecdotal experience coupled with intellectual assessment forces a great physician to evolve for the betterment of his or her patients. If one were to only provide treatment that was proven, then innovation would not be possible. This is the Achilles heel of evidence-based medicine.

Medical research allows us to understand responses to treatments and helps us determine which treatments are better as a *whole.* But we must remember that this does not determine which treatment is best for each *individual* since we have to take into account the anatomy, physiology, biological makeup, social and psychological situation, and personal goals of each patient. It is a truly customized and individualized approach that produces the best result for each individual patient when provided by a competent medical professional. This is critical to achieve success in spinal healthcare

We should always be striving to gain more knowledge and to be critical of the available treatments, but leaving the final treatment decision between the patient and physician to determine what is best in each situation. Evidence-based medicine can help us make informed decisions but is never an absolute answer. Patients are unique and should be treated as such.

SECTION 1

# Non-surgical Decision-Making

# IS PHYSICAL THERAPY FOR LOW BACK PAIN WORTH YOUR TIME?

**Larry Grine, DPT**
*Virginia Therapy and Fitness Center*

The prevalence of low back pain is staggering. Approximately four out of five people will experience lower back pain during their lives. It is one of the most common reasons for healthcare visits in the United States. What causes low back pain, why is this such a widespread problem, and what can we do about it?

## LOW BACK BASICS

The spinal column has 24 vertebrae that move and are located above the fused segments of the sacrum and tailbone, which do not move. Lower back pain (LBP) is generated from the lowest five motion segments between the lowest rib down to the pelvis/tailbone region, called the lumbar spine. Segmental nerves related to this area of the spine will innervate the back, buttocks, hips, and legs. As a result, pain can be referred into these areas.

Injury to the low back region can cause **abrupt** mechanical or chemical damage/irritation to the intervertebral discs and/or vertebrae, compression of nerve roots, and poor movement of the spinal joints. The intervertebral disc is round-shaped, made of fibrocartilaginous material, and located between the vertebral bones of each segment. The disc will absorb compressive, rotational, and shearing forces based on the type of movements, postures, and positions a person moves in and out of each day. Discogenic low back pain refers specifically to pain coming from one or more of the intervertebral discs in the lumbar spine.

The normal aging process will cause **gradual** changes to our bodies. For many, these are gradual changes to their spinal structure, spinal alignment, intervertebral discs, and/or surrounding muscular system. Symptoms related to discogenic pain are often associated with postures, positions, and movements that increase pressure inside the intervertebral disc which include: sitting, squatting, bending forward from the waist, and coughing or sneezing. Disc degeneration does not usually cause significant pain in the early stages. However, LBP and other symptoms may occur in more advanced stages of disc degeneration.

## PHYSICAL THERAPY FOR BACK PAIN

The symptom of discogenic LBP is simply localized pain in the low back region, and primarily does not radiate down the leg(s) until the degeneration advances to the point that it causes compression to the spinal nerves. Some degeneration to the intervertebral disc can be caused by poor movement patterns when compensating for changes in another area of the body. For example, a stiff hip will often cause patients to walk with a limp. The abnormal gait pattern can increase stresses throughout the body and cause accelerated degeneration of the intervertebral disc. This highlights the importance of a whole body evaluation and approach, which good physical therapy will accomplish.

What does 'good' physical therapy look like for the low back? The most successful physical therapy routines for discogenic LBP should include:

1. **Early intervention** — from the time of injury or onset of pain.

2. **A full body biomechanical examination** — to accurately identify pain triggers and identify dysfunctional movement patterns, postures, and positions. Also to identify any muscle imbalances caused by weakness or overactive muscles.

3. **Tailored Treatments** — to meet the needs of each individual, including:
   - To eliminate pain triggers
   - To reduce inflammation
   - To provide the body with an optimal healing environment

4. **Comprehensive Treatments** — the most successful treatments use a combination of modalities:
   - Manual therapy
   - Targeted exercise
   - Strengthening
   - Functional restoration
   - Lifestyle modification coaching to maintain good spinal hygiene, such as:
     - Weight loss to achieve a "back-friendly" weight
     - Smoking cessation
     - Daily home physical activity

## TIMING MAKES A DIFFERENCE

Oftentimes, patients with lower back pain face significant delays in getting to a physical therapist, which slows the recovery process. These delays are often related to a patient self-treating or seeking treatment from providers that do not specialize in spinal healthcare, and 6-10 weeks quickly pass with continuing or worsening symptoms. This delay may cause a reduction in the ability to remedy LBP quickly and can make compensatory patterns more difficult to resolve once proper spine physical therapy is initiated.

## THE RESEARCH

A study titled "Physical Therapy as the First Point of Care to Treat Low Back Pain" was published in the *Health Services Research Journal* in December 2018. They found that patients who worked with a physical therapist as the **first** treatment approach had a lower probability of needing:

- Opioid prescriptions
- Advanced imaging services
- Emergency room visits

Patients included in this research were also found to have significantly lower out-of-pocket costs. This article reviewed data from 150,000 insurance claims and concluded that patients with low back pain are better off seeing a physical therapist first.

Many articles highlight effective treatment of lower back conditions from treating areas adjacent to the lower back, called regional interdependence. Regional interdependence is simply the cross interactions that occur between different regions of the body that connect to one another, such as the lower back and hips, knees, ankles, and feet. Research has shown that inflamed discs can result from an overload of biomechanical stresses from other areas of the body and increase the rate of disc degeneration.

## CONCLUSION

There will always be cases where physical therapy alone does not resolve the problem, and the need for additional treatments is warranted. It takes an excellent team approach of physical therapists and spinal specialists who see patients frequently and work collaboratively to identify and prescribe the proper treatment. The largest hurdle to a quicker recovery might be the easiest to overcome. The solution is simple…evidence shows that patients need to get to a good therapist as early as possible after a low back injury or the onset of significant pain without an obvious injury. A good recommendation is to also have an excellent spinal surgeon in mind in case your LBP doesn't improve with conservative care.

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# REGENERATIVE MEDICINE IS A NON-SURGICAL AND DIRECT TREATMENT FOR DISC PAIN

**Niteesh Bharara, MD**
*Virginia Spine Institute*

**Rikin Shah, BS**
*Trinity School of Medicine, PGY-4*

## MODERN DAY ADVANCEMENTS

Regenerative medicine embodies a distinct and major advancement in modern medical care. Therapies from this medical field are expected to transform the treatment paradigm of musculoskeletal problems. For decades, most musculoskeletal treatments have not been aimed at eliminating the **root cause** of an ailment, but have instead addressed only the **symptoms** of a particular ailment. With advances in the field of regenerative medicine, trained physicians are now able to modify and address the underlying cause of a patient's problem, instead of simply treating symptoms which arise from a problem. There is mounting evidence to show that regenerative medicine may be superior to traditional medicine in some cases. Over the course of many years, these revolutionary therapies have gone from novel ideas to what are now proven, evidence-based treatments that have produced successful outcomes for problems which were unable to be properly addressed.

## LOW BACK PAIN

Lower back pain is the leading cause of global disability, and lumbar disc degeneration is the most common cause of disability in the United States — it also happens to be the cause of 40% of chronic lower back pain cases. Intervertebral discs, which lie between the vertebral bodies, act like pads or "shock absorbers" for our body's movements; each of those discs is composed of an outer band that resembles a tire (annulus fibrosus) and an inside substance that resembles gel (nucleus pulposus). Though most disc degeneration remains asymptomatic, pain emanating from the discs (discogenic back pain) is very often the cause of both acute and chronic lower back pain.

Normally, discogenic back pain (commonly referred to as "disc pain") can be treated successfully with traditional treatments such as physical therapy. Despite this great success rate, it is estimated that approximately 10% of disc pain sufferers fail to improve with both traditional medical treatments and physical therapy. It is important to remember that disc pain arises for a number of reasons, including:

- bodily trauma (sports injuries, laborious work, accidents)
- age-related reasons — better known as "wear and tear" to the vertebral disc (those "shock absorbers")

More often than not, injuries will go unnoticed or ignored by a patient. With time, an injury can certainly worsen and lead to various degrees of pain that impedes one's ability to have a high-quality and active life.

## THE PROBLEM WITH TRADITIONAL (INDIRECT) TREATMENTS

Traditional non-operative methods used to treat discogenic low back pain are physical therapy, analgesics (pain-relievers), anti-inflammatory injections, and orthoses (braces). These treatments will often need to be used in combination and may need to continue over a long period of time for patients to get any appreciable form of pain relief. This type of regimen may require a patient to sustain multiple **physical therapy** appointments, medications, and a back brace, which is often unsustainable and becomes inconsistent in the long-term.

Over-the-counter and prescribed pain **medications** are not good options due to limited efficacy and side effects. Although prescription pain medicines have a higher efficacy — the side effects, tolerance, and dependency make them bad choices for extended use. **Orthoses** such as back braces are expensive, uncomfortable, and take several rounds of trial and error to find the right fit for a patient. These may also weaken the core strength over time, worsening the back pain. **Injections** such as steroids require that an experienced specialist administer them and to do so rather often. Even when patients are able to achieve pain relief from any of the aforementioned treatments, there is zero structural improvement created for the damaged disc. So, that disc remains damaged and at risk of causing pain and further problems at any given moment.

## THE PROMISE OF REGENERATIVE (DIRECT) TREATMENTS

With the emergence of regenerative medicine procedures, disc anatomy can be modified and disc pain that failed to be resolved using traditional methods can be resolved almost permanently. There are two main substances used in regenerative medicine treatments. The first substance is platelet rich plasma **(PRP)** which is literally just a concentration of the platelets mixed with growth factors found in a patient's blood. The second substance is called bone marrow aspirate concentrate **(BMAC)** which is a concentration of a patient's extracted bone marrow and contains the growth factors and mesenchymal stem cells that are stored there. Either of these two substances can be precisely injected into the damaged disc in order to alter the disc structure and its environment — essentially regenerating a painful disc into a disc that does not hurt. Treatment is typically short in duration and consists of a simple injection procedure with very little subsequent downtime. Great success has been found in treating patients that:

- cannot get back into their desired activities because of back pain
- have their backs give out frequently
- experience chronic pain
- have no other hope outside of surgery

## THE FUTURE IS HERE

Before the evolution of the regenerative medicine field, good treatment options were lacking for disc pain sufferers who had been failed by various conservative measures. Regenerative medicine therapies are life-altering for numerous demographics of patients; most importantly, these therapies have given patients the ability to return to pain-free lives in relatively short time frames and without undergoing invasive surgical procedures that carry with them subsequent side effects and long recovery periods.

The future of regenerative medicine is bright. As more patients continue to experience positive outcomes, regenerative medicine procedures will increasingly replace invasive surgical procedures and more patients will seek out the ability to have their body heal itself through innovative regenerative medicine techniques.

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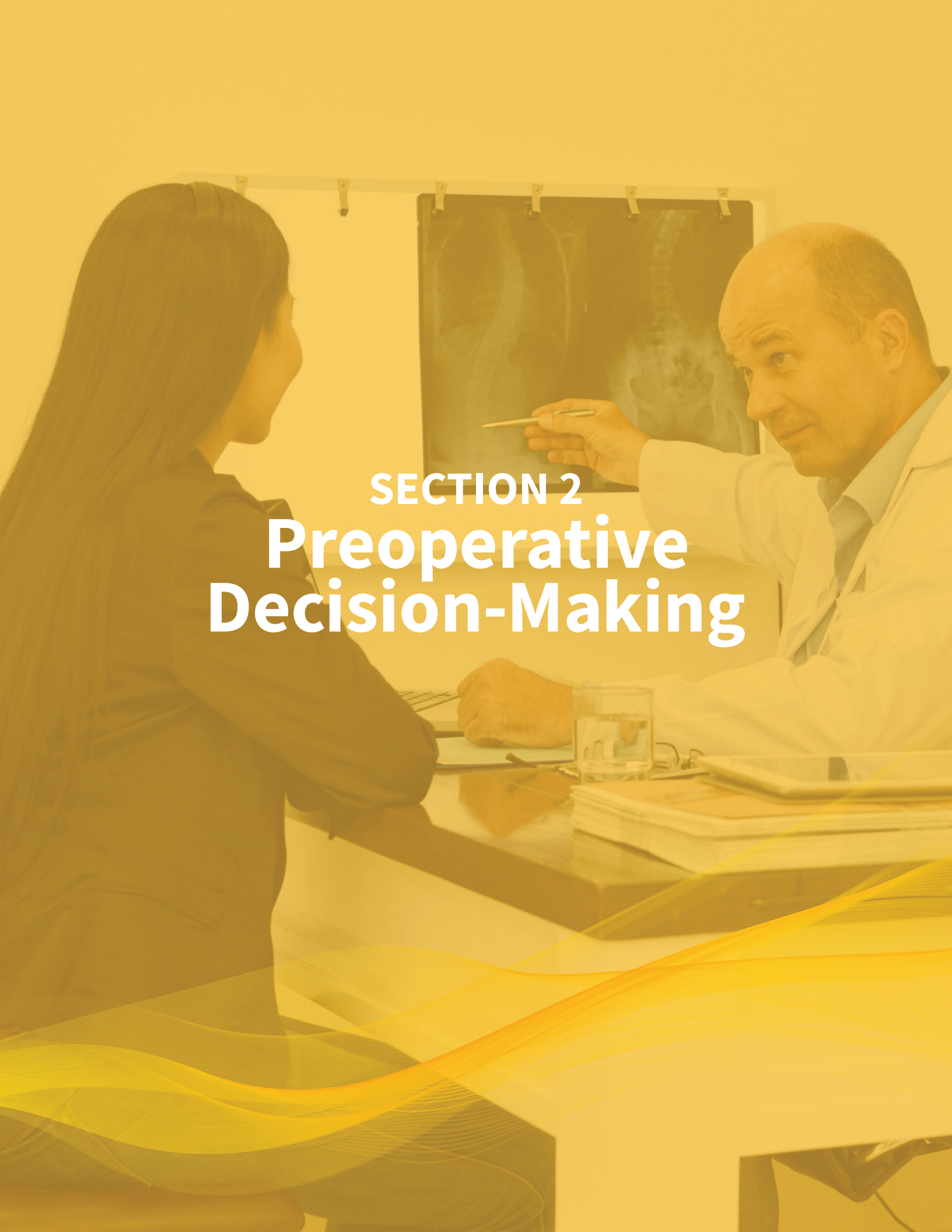


SECTION 2

# Preoperative Decision-Making

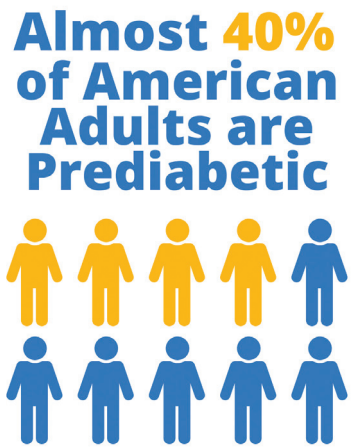

# CONTROLLING YOUR DIABETES HAS GREAT BENEFITS

**Jesse Shen, MD**
*Virginia Mason Medical Center*

**Rajiv Sethi, MD**
*Virginia Mason Medical Center*

## THE BAD NEWS

Type 2 diabetes (diabetes mellitus) is a chronic disease that tremendously impacts patients and society. The Center for Disease Control (CDC) estimates that 11.3% of the American population has diabetes and that almost 40% of the adult population in America has pre-diabetes[1]. This number is staggering and shows how common this disease is.




Not only is it common, but diabetes has severe effects on a person's health and well-being. The impact of diabetes is due to its complications if left untreated. Complications such as heart attacks and strokes can increase patients' mortality risk. However, when diabetes is well-controlled, some of these negative effects can be reversed in this patient population[2].

The impact of diabetes is also expressed in spine diseases and spine surgery. Patients who have uncontrolled diabetes are at higher risk of surgical complications. These are serious considerations as it increases the risk of infection, heart attacks, and blood clots which puts patients at higher risk of mortality after surgery[4]. Moreover, the average hospital stay for patients with uncontrolled diabetes is longer. It is clear that diabetes can seriously impact spine patients.

Not only does uncontrolled diabetes affect complications after surgery, but it could also impact the quality of life and outcomes following surgery. Recent articles have shown that patients with diabetes have worse clinical outcomes compared to

those who do not have diabetes. These effects were felt two years after surgery[5]. Diabetes impacts all facets of a patient's postoperative well-being, from complications to outcomes.

## THE GOOD NEWS

Fortunately, care teams can mitigate these adverse effects by helping patients adequately control diabetes **before** spine surgery. A recent publication showed that controlling diabetes to specific targets can improve outcomes and reduce complications following spine surgery[6]. Also, it has long been known that when diabetes is controlled, it can decrease the complications related to this disease[7]. Furthermore, well-controlled diabetes can improve quality of life, short-term symptoms, and even economic considerations such as less absenteeism for workers[3]. The benefits of diabetes control are enormous for patients. Therefore, managing diabetes is critical for a patient's well-being, not only for spine surgery.

The evidence is compelling for patients to control type 2 diabetes adequately. Improving a patient's health by managing diabetes goes well beyond the impacts of spine surgery. Each patient needs to have their diabetes well-controlled to have the best surgical outcome and overall well-being. We recommend that patients consider and follow recommendations for proper blood sugar control for diabetes.

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# THE IMPACT OF OBESITY IN COMPLEX SPINAL RECONSTRUCTION

**Patrick A. Sugrue, MD**
*Advocate Health Care*

## OBESITY IS PREVALENT IN THE US

The rate of obesity in the United States has steadily increased over the last few decades to the point where more than one third of adults in America are considered obese.[1,2] We define obesity using a measurement called body mass index (BMI), which takes into account one's height and weight. The National Institute of Health defines "obese" as a BMI ≥30 kg/m$^2$ and "morbidly obese" as a BMI ≥40 kg/m$^2$. While the rate of obesity has increased, so has the prevalence of patients with adult spinal deformity, including approximately 5 million Americans disabled with a spine disorder.[1,3,4] Associated with the increase in spine-related morbidity, we have seen an increase in the number of spinal surgeries being performed each year with an increase of 62.3% from 2004-20015.[1,5,6]

## RISKS OF COMPLEX SPINE SURGERY

The impact that adult spinal deformity has on one's life is significant and can lead to a significant decline in overall quality of life.[7] Surgical intervention for adult deformity has been shown to improve overall quality of life quite significantly. However, there are some very significant challenges that accompany any spine surgery, especially procedures designed to treat adult spinal deformity with long construct fusion and complex reconstruction. The reported complication rates for surgery involving complex reconstruction can be as high as 95%.[8] When we counsel patients prior to undergoing such an operation we often say "it's not if but when a complication will occur". Despite that, success rates for patients undergoing complex reconstruction for adult deformity are typically quite good when compared to nonoperative treatment.[9]

When planning for surgery and counseling a patient and their family, we try to focus on the risks versus benefits of such an operation. The risks of surgery can occur during the operation or postoperatively and encompass medical, surgical/technical, and social factors that accompany a complex operation and the challenging recovery that follows. We all want to reduce risk and maximize benefit and thus we try to modify or optimize all of the risk factors that go into the planned operation. Nonmodifiable risk factors include things like age and magnitude of deformity. However, one modifiable risk factor that can have a significant impact on outcome is obesity.

## OBESITY IS A MODIFIABLE RISK FACTOR

Obesity as a risk factor has been studied across multiple surgical disciplines and has been shown to increase

complication rates. Specifically in adult spinal deformity surgery, obesity (BMI ≥30 kg/m$^2$) has been shown to be an independent predictor of increased risk for major complications and wound infections, as well as blood loss and longer operative times.[8,10] Not surprisingly, along with the increased complication rate comes a higher cost of care and higher cost per quality-adjusted life years. Reports have also shown an increased rate of revision surgery over the long term in obese patients compared to the nonobese.[11, 12]

Despite the negative association with obesity, both obese and nonobese patients experience a significant increase in overall quality of life when comparing pre-operative to post-operative patient reported quality of life outcome measures.[8, 10, 11] However, obese patients experienced less overall magnitude of improvement and a lower rate of improvement over time.[8]

With that in mind, prior to surgery we want to optimize a patient as best as possible. When discussing these issues with patients prior to surgery I typically use the following analogy. If you plan to run a marathon, you don't just get out of bed one day and show up at the starting line. You train for it. Spine surgery, specifically complex reconstruction, is like running a marathon and is a massive stress to one's body. Thus, you want to train and prepare your mind and body for the marathon.

## PREHAB

Reducing obesity is one way to significantly improve your likelihood of achieving a good sustainable outcome. We call this process "prehab." Patients also benefit greatly from improved nutrition and exercise. We will often have our nutritionists work with the patients to optimize their nutritional status and create a balanced diet. Likewise, we encourage regular physical activity and aerobic exercise to prepare for the stress of an operation. For patients who cannot tolerate much activity due to their obesity and/or spine-related disability, we encourage aquatic therapy, which can take some stress off the spine by being in the water but allows the patient to increase their heart rate and gain the benefits of the aerobic exercise.

## RISK-BENEFIT EQUATION

In conclusion, obesity plays a major role in the risk versus benefit equation that must be weighed prior to undergoing any operation, particularly a complex reconstruction. Fortunately, obese patients can gain similar benefits to nonobese patients, but their operative and post-operative course may be more difficult because of the obesity. Therefore, we want to optimize these modifiable risk factors as much as possible prior to surgery to increase the likelihood of achieving the desired outcome.

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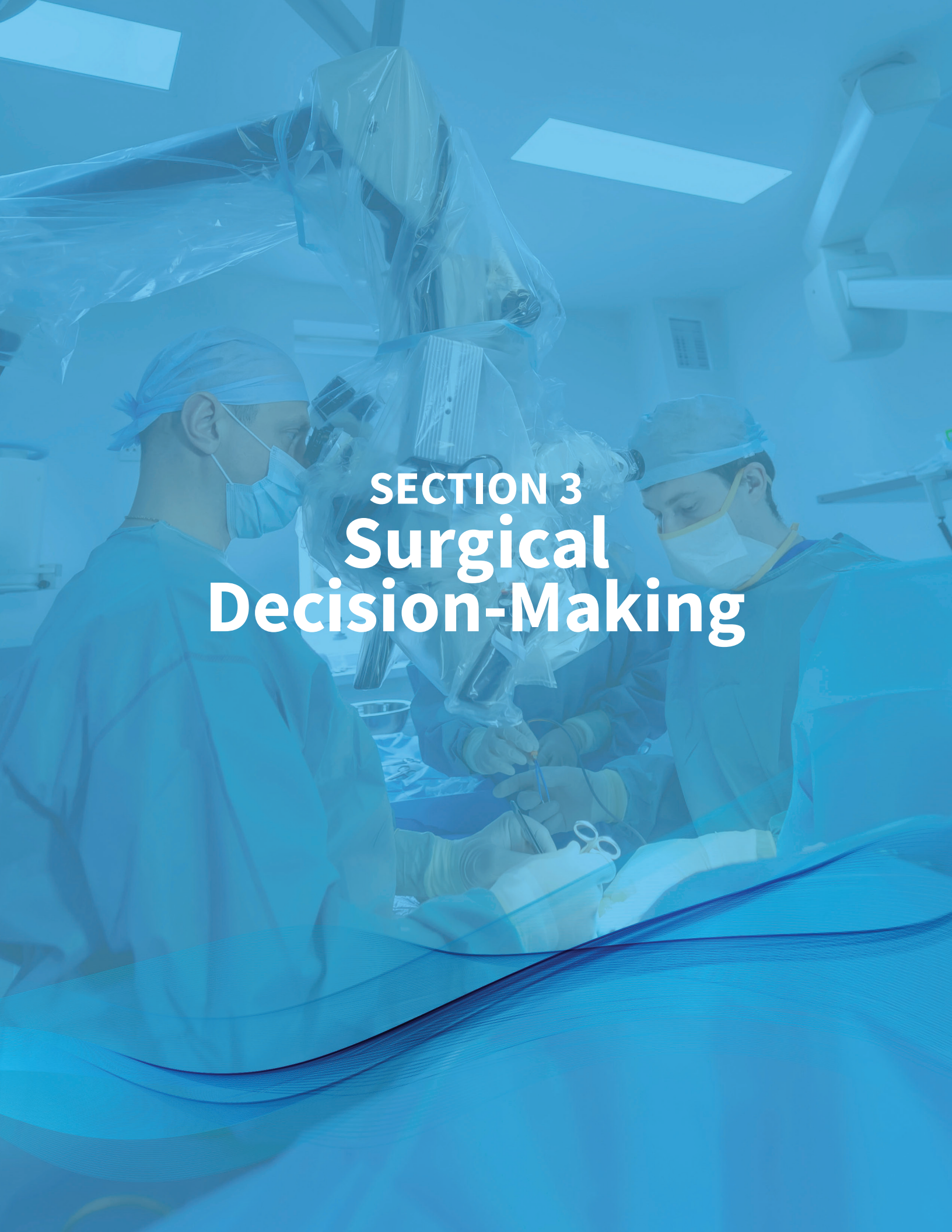


# SECTION 3
# Surgical Decision-Making

# ADVANTAGES OF ROBOTIC-ASSISTED SURGERY: A PATIENT PERSPECTIVE

**Jeffrey L. Gum, MD**
*Norton Leatherman Spine Center*

***"Are you going to use the robot?"* is a common question encountered in my office.** Typically, my answer is "yes, of course" and then I go on to explain the procedure in detail and the benefits of utilizing such technology. Robotic-assistance in spine surgery is a relatively new technology that is emerging, and for obvious reasons. Beyond the typical marketing hype behind robotics, there is well-documented clinical value that patients experience when surgeons incorporate this technology in their surgical workflow and operating room.

Currently, the capabilities of all spinal robotic platforms are primarily focused on guiding the placement of screws into a specific part of the spine called the pedicle. Pedicle screws are a type of fixation placed to hold the spine in a fixed position while the vertebrae fuse together. The goal of a spinal fusion is to eliminate instability or motion that causes pain. There are numerous ways surgeons can place pedicle screws, and some of the most common methods include:

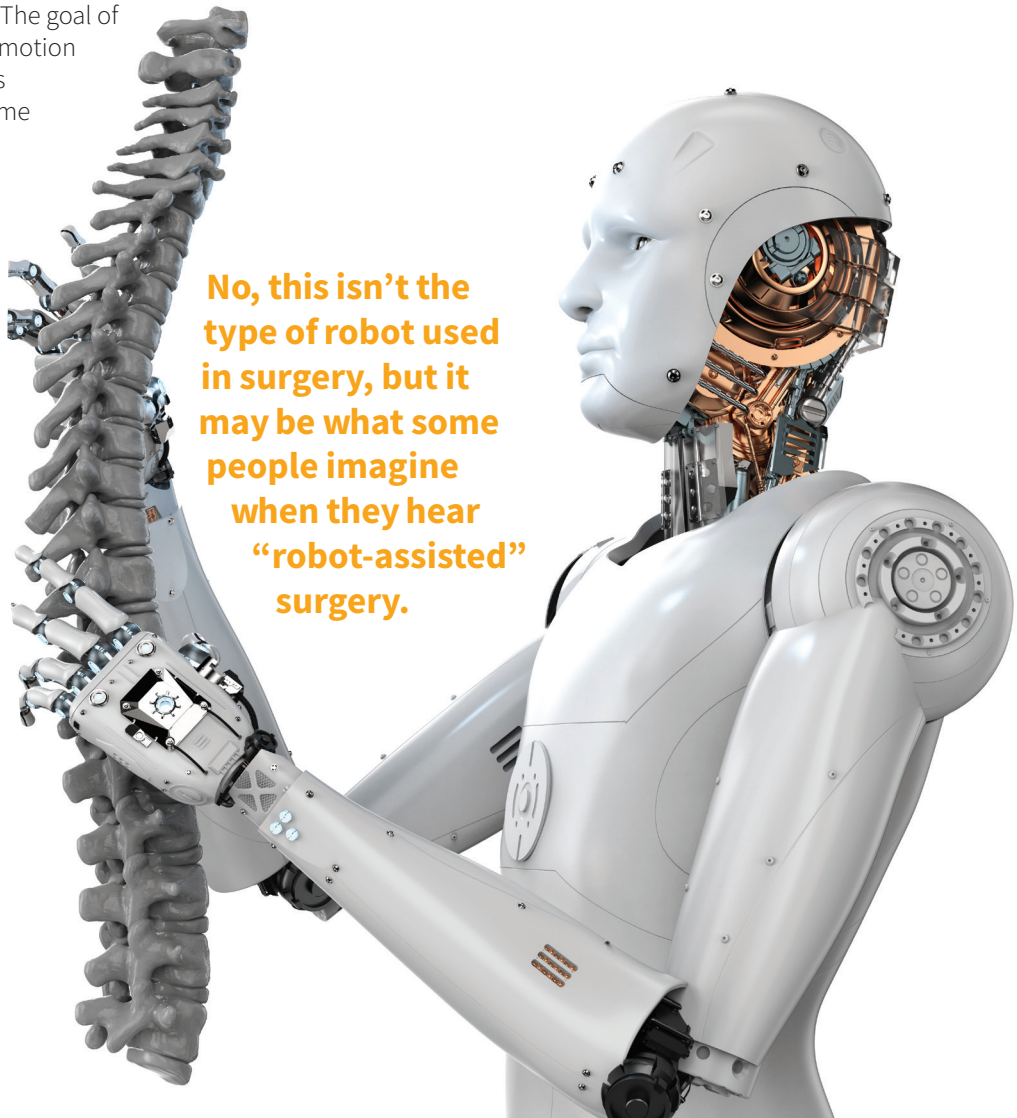
- **freehand:** the surgeon uses tactile feedback from their hands and the visualization of surrounding landmarks to place screws
- **fluoroscopy-assisted:** the surgeon uses live x-ray to place screws
- **navigation-assisted:** the surgeon uses 3D imaging to place screws
- **robotic-assisted:** the surgeon places screws through the arm of the robot

## BENEFIT #1: ACCURACY

Each of these techniques have been very well studied and robotic-assisted, along with navigation-assisted, are consistently the most accurate. Why is this important? If a screw is placed incorrectly, it could cause a permanent neurologic deficit which may result in pain, weakness, and lead to another surgery to reposition the bad screw. Of course not all misplaced pedicle screws lead to this result, but why would surgeons not want to minimize this possibility and utilize the best available technology when appropriate?

## BENEFIT #2: MINIMALLY INVASIVE

The second reason, and my favorite part of utilizing robotics in spine surgery, is that it allows the surgical goals to be accomplished in a more minimally invasive (MIS) and efficient manner. Over the last few decades, spine surgery has adopted a lot of techniques to improve the postoperative recovery process. The goal of these MIS techniques is to minimize disruption of the spinal muscles and utilize smaller incisions but still achieve the desired outcome. Robotic-assisted surgery has really helped surgeons incorporate these



**No, this isn't the type of robot used in surgery, but it may be what some people imagine when they hear "robot-assisted" surgery.**

techniques and deliver better outcomes for patients. These MIS procedures allow patients to return to work and normal activities more quickly.

## BENEFIT #3: REDUCED RADIATION

A third advantage that is not noticed by the patient, but is very important, would be reduction in radiation exposure. It is well known that excessive radiation exposure can have detrimental long term effects such as increased risk for certain types of cancer. Most patients that need to undergo a spinal fusion have been exposed to quite a bit of radiation already. Minimizing radiation exposure during the actual spinal fusion procedure itself can be beneficial for long-term health and potentially reduce the cancer risk.

## BENEFIT #4: REDUCED TIME

The last reason that highlights the advantages of robotic-assisted spinal fusion surgery is reduction in the length of the surgery or OR time. OR time alone can be a risk factor for complications after surgery. In essence, if a surgeon can perform the same surgery quicker while still maintaining safety, the outcome is better. Less time under anesthesia expedites the recovery process and reduces the risk for medical complications in the postoperative period.

## INFORMED DECISION-MAKING

Overall, surgeons that incorporate robotic-assisted surgery into their toolbox of techniques for spinal fusion can potentially deliver more consistent, reliable, and better outcomes for patients undergoing fusion procedures. From a patient perspective, it is important to not just jump to any

**OR time alone can be a risk factor for complications after surgery. In essence, if a surgeon can perform the same surgery quicker while still maintaining safety, the outcome is better.**

spine surgeon that claims they use robotics in their practice, but to have a conversation with them regarding how they utilize the technology. Appropriate questions include:

- How often do they use robotics?
- Why do they suggest using it for your procedure (or why not)?
- What benefits have they observed in similar patients or surgeries?

These baseline questions will serve as a good dialogue between patient and surgeon to get all questions answered and both sides comfortable with the shared decision-making process for surgery.

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# AUGMENTED REALITY SPINE SURGERY? THE FUTURE IS NOW

**Camilo A. Molina, MD**
*Washington University School of Medicine*

Move over Superman, x-ray vision isn't just for superheroes anymore. A growing number of surgeons using augmented reality (AR) surgical navigation are at the forefront of recent spine surgery innovation. We asked Dr. Camilo Molina, Assistant Professor of Neurosurgery and Orthopedic Surgery at Barnes-Jewish Hospital in St. Louis, MO and one of the pioneers behind Augmedics' xvision spine system, to open our eyes to this futuristic-sounding technology. Here are the takeaways.

**Augmented reality lets surgeons "see" through their patients' skin and tissue.** Augmented reality spine surgery allows surgeons to see patients' anatomy as if we have "x-ray vision." Similar to using GPS, we are then able to accurately and in real-time navigate instruments and implants during spine procedures. Unlike traditional navigation systems, AR allows us to do this while keeping our eyes directly on the patient, rather than looking over at a computer screen.

**This novel AR technology is actually pretty simple.** For something that sounds like it's out of an episode of *Star Trek,* AR spine surgery is beautiful for its simplicity. We take a 3D intraoperative scan which is fed into an AR headset. A 3D visualization of the patient's anatomy and 2D navigation data is then superimposed onto the surgical field, which we use to efficiently, accurately, and safely place spinal implants.

**Augmented reality spine surgery is safe and highly accurate.** In spine surgery, accuracy is critical. The spine is responsible for the uniquely human upright bipedal structure, but just as importantly, it safeguards the super conduction highway of nerves that allows our brains to communicate with our bodies. We often place implants with minimal room for error to avoid injuring these structures. This is particularly true in minimally invasive surgery, where we insert implants percutaneously, via small incisions in the skin.

We did a study back in 2020 to assess the accuracy and precision of percutaneous screw placement using AR navigation. The results, which were published in the *Journal of Neurosurgery,* found the overall clinical accuracy of AR navigated pedicle screw placement was 99.1%. Another study on AR navigated screw placement published in the *Global Spine Journal* earlier this year reported no adverse effects, no revisions, and no complications and further concluded that AR was a safe and accurate tool for spinal fixation. For spine surgeons, this level of safety and accuracy is paramount.

**Augmented reality spine surgery eliminates surgeon attention shift and keeps focus directly on the patient.** Let's go back to the GPS example for a minute. Imagine driving a vehicle while using GPS. Would you want the GPS information superimposed on your windshield so you're always looking at the road? Or would you prefer to constantly look away to your console or down at your phone? In surgery, we call this attention shift, and there's a lot of data that shows that this kind of distraction negatively affects both cognitive and motor tasks. By using the AR headset, we eliminate it. The patient's 3D anatomy and navigation data are superimposed directly onto the surgical field, so we are always looking directly at the patient.

**Unlike traditional navigation systems, AR allows us to do this while keeping our eyes directly on the patient, rather than looking over at a computer screen.**

**Augmented reality navigation enables minimally invasive surgery (MIS).** There's a growing trend in spine surgery toward MIS procedures in recent years, and for good reason: the myriad of benefits include shorter hospital stays, faster recovery times, less blood loss, reduced postoperative narcotic use, lower infection rates, and cost savings, to name a few. In these percutaneous procedures we can't physically see the anatomy, so we rely on technology to safely guide our instruments and implants through the correct trajectories. This is where surgical navigation comes in. And what we're seeing with AR navigation specifically, is that the learning curve is so shallow, we're actually empowering surgeons to make that jump to MIS.

**Augmented reality spine surgery is already in use in ORs across the US, and it's ready for primetime.** Leonardo da Vinci said, "Simplicity is the ultimate sophistication." AR navigation is so instinctive and easy to learn. For example, I've had residents who've never navigated before pick it up on the first try. We have a novel technology that enables surgical navigation to be easily and rapidly adopted; we know it's safe, we know it works, and it's actually more economically accessible than the alternatives. Xvision has been used to treat +2,000 patients in over 50 hospitals across the US and those numbers are climbing every day. The fact that AR navigation is being adopted is evidence that surgeons want to be on the cutting edge of surgical technique, they want to be advancing the field. They want to push that envelope of delivering a higher standard of care to their patients. Augmented reality navigation can do that. What the iPhone did for smartphone adoption, this will do for navigated spine surgery.

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# EVIDENCE SUPPORTS AUGMENTED REALITY-ASSISTED SPINAL FUSION USING A HEAD-MOUNTED DEVICE

**Tarek Yamout, MD**
*Virginia Spine Institute*

**Ehsan Jazini, MD**
*Virginia Spine Institute*

Augmented Reality (AR) is a novel form of navigation technology that spine surgeons are increasingly using during fusion procedures. For context, many instrumentation approaches are used in spine surgery, including: freehand technique, fluoroscopic guidance, computer-assisted navigation (CAN), and robotic-assisted navigation (RAN). AR works by projecting computer-generated images of patient anatomy and surgical tracking information onto the surgeon's retina, essentially combining a virtual object with the "real world". In the United States, the first head-mounted AR (HMD-AR) device was FDA approved in 2019.

## WHAT ARE THE ADVANTAGES OF USING AR?

**Safety and Accuracy**

The goal of any spine surgery, and accompanying advances in technology, is to ensure patient safety and optimal treatment outcomes. Although AR is a relatively new technology in the realm of spine surgery, there have been several reported advantages with its use. One advantage is accuracy. Pedicle screws placed with the assistance of HMD-AR devices have been demonstrated to be clinically accurate. Accuracy is graded by whether a screw deviates from its planned trajectory. The majority of screws that have been clinically assessed using AR have achieved the highest accuracy rating (grade A). Additionally, AR has been shown to be a safe procedure. Studies have demonstrated that the rates of intraoperative and postoperative complications are very low. This means the risk of needing a revision surgery to address any complication is also reduced.

**Radiation Exposure**

Radiation exposure is a major concern for both patients and surgeons during spine surgery. An advantage with AR is the limited need for live x-ray during surgery, which differs from other more traditional surgical techniques. It is important to note that a patient will still be subject to the radiation of a 3D scan, which is unavoidable in utilizing this technology, however the degree to which one would be exposed is significantly reduced with AR.

## TAKEAWAY POINTS

There have been incredible advances in spine navigation technology over the past three decades, and AR presents itself as a viable modality for pedicle screw guidance. It is important for spine patients to have a general awareness of the current technology to have an informed discussion on the advantages and disadvantages with their surgeon.

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# WHICH NECK SURGERY TO CHOOSE: CERVICAL DISC REPLACEMENT OR FUSION?

**Saman Shabani, MD**
*Medical College of Wisconsin*

## FUSION DETAILS

Traditionally, degenerative disc disease of the cervical spine (neck) that causes radiating arm symptoms (cervical radiculopathy) or symptoms associated with spinal cord impingement (myelopathy) is treated with anterior cervical discectomy and fusion **(ACDF)**. The goal of ACDF is not only to remove the pressure from the nerve roots and/or spinal cord, but also to form a bony fusion across the discectomy site. This procedure usually involves:

- complete discectomy to remove pressure on the nerve roots and/or spinal cord
- placement of a spacer to fill the discectomy site
- placement of a plate with screws across the discectomy site
- packing the spacer with bone graft

Placement of the spacer and plating with screws and ultimately formation of bony growth (fusion) will result in a loss of motion across that segment where the discectomy is performed. This leads to higher stress levels across the unfused segments of the spine and may accelerate the degenerative process at those segments. When this occurs, patients may require additional surgery to address the faster degenerative process stemming from the original ACDF.

## DISC REPLACEMENT DETAILS

In the last decade, anterior cervical disc replacement **(ACDR)**, also known as cervical arthroplasty, was introduced as an alternative procedure to ACDF. The goal of ACDR is to relieve the pressure from nerve roots and/or spinal cord while preserving the motion across the discectomy site. The procedure involves discectomy and placement of a motion-preserving implant. The preservation of motion reduces the stress load at the levels above and below the discectomy site, preventing the accelerated degenerative process seen in ACDF.

## OTHER CONSIDERATIONS

Anterior cervical disc replacement has other advantages compared to ACDF. Although both have quick recovery times, patients with ACDR can return to more strenuous activities sooner than ACDF. In ACDF, a longer period of recovery is needed for fusion to occur.

Not every patient will be an ideal candidate for ACDR. Currently the Food and Drug Administration (FDA) has approved ACDR for up to 2 disc levels. Usually, ACDR is performed on individuals who are younger and do not have:

- facet joint degeneration
- poor bone quality (osteoporosis)
- underlying instability
- spondyloarthropathies
- infection
- known malignancy

Overall, both ACDR and ACDF are very effective surgeries, but patient selection for the appropriate surgery is essential for a successful outcome. This highlights the importance of a good patient-surgeon relationship to discuss these options and the evidence behind them.

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# TO HAVE DISC SURGERY OR NOT TO HAVE DISC SURGERY? THAT IS THE QUESTION...

**Neville Alleyne, MD**
*OSNC Orthopedic Specialists of North County*

## DISC HERNIATIONS EXPLAINED

The spine is made up of alternating bones and discs, where the bones are strong and provide support while the discs are pliable and provide movement. Discs are made up of an inner cartilaginous core surrounded by a thick outer ligamentous ring. A lumbar disc herniation occurs when part of the inner core breaks through the outer ligament in the lowest part (lumbar) of the spine. Lumbar disc herniations most often cause leg pain because a nerve becomes irritated and/or compressed by the herniation. Lumbar disc herniations occur frequently in the age groups ranging from 20 to 50 years. Approximately 90% of lumbar disc herniations occur at the lowest two lumbar disc levels, L4/5 and L5/S1.

## NON-SURGICAL TREATMENTS

Fortunately, there are extensive non-surgical treatment options which are often successful at improving or eliminating symptoms, including the use of anti-inflammatories, anti-spasmodics, mild/short-term opioid analgesics, physical therapy, chiropractic treatment, acupuncture, and/or the use of pain management procedures such as epidural injections, facet injections, or radiofrequency ablation. Non-surgical treatment can achieve good results, but patients must do their part in assisting with recovery. These basic interventions can be successful at staving off the need for surgery:

- Reduce weight (BMI)
- Eat appropriate meals, especially those afflicted with diabetes
- Quit smoking/nicotine
- Perform adequate exercise and core strengthening

## SURGICAL TREATMENT: MICRODISCECTOMY

There are approximately 450-500 thousand discectomies performed in the United States each year to surgically treat lumbar disc herniations. Microdiscectomy can be considered after an appropriate period of conservative treatment (2 to 3 months) fails to provide significant improvement, but would be considered sooner if there is a progressive neurologic deficit. Such a deficit could include weakness in the:

- Ankle
- Foot
- Toes
- Hamstring
- Quadriceps
- Hip flexor

Although less common, urgent surgical intervention is warranted in the event of progressive neurological deterioration such as loss of bowel or bladder function, loss in perineal sensation, and weakness in the lower extremities. This rare condition is called, "cauda equina syndrome."

When surgical intervention is indicated, microdiscectomy is a great surgical option. This type of surgery is small (micro) and can be done using a high powered microscope or through a cannulated tube with minimal disruption to the soft tissues, resulting in a very small incision that facilitates faster recovery. During surgery, the piece of displaced disc material is removed relieving the pressure on the nerve. Patients can leave the ambulatory center or hospital the same day of surgery. Initiating physical therapy within 2-3 weeks after surgery can be very helpful in getting the muscles to recover and allowing nerve function to return.

These procedures can sometimes be completed within an hour and other times can take twice as long. Performing an elegant microdiscectomy can be one of the more challenging operative procedures we perform as spine surgeons. With limited resection of bone and/or ligament, this procedure will impart minimal disruption and instability to the spine. As with all procedures, when done well, it is extremely gratifying.

Microdiscectomy procedures have a success rate of 70-90% and the best surgical outcomes occur in patients that do not postpone surgery longer than 6 months to 1 year. Beyond one year of symptoms, success can drop down to approximately 80%. I usually tell my patients they can expect an 80-85% success rate with microdiscectomy.

## RISKS AND COMPLICATIONS

Although a first time microdiscectomy has a very high success rate, there is a chance that another disc herniation occurs in that same location (called a recurrent disc herniation). The rate of recurrence can be 10-25% within the first year after the initial surgery. This is usually related to a weak area in the ligamentous ring allowing more disc material to extrude through, resulting in a re-herniation. Additional surgical intervention may be needed in the event of a recurrent disc herniation.

Occasionally, scar tissue can develop after surgery causing similar nerve symptoms over time. In these situations careful history, physical examination, and imaging may be helpful. Other potential surgical complications include but are not limited to: infection, battered nerve root syndrome, cerebrospinal fluid leak, arachnoiditis, epidural fibrosis, or residual pain secondary to failure in retrieving all the disc fragments that herniated. Although the risk of these complications is often low, each patient should discuss their individual risk with their surgeon.

## CHOOSING A SURGEON

Choosing the best surgeon can be daunting, but do not be afraid to ask questions, such as:

- How many of these procedures do they perform each year?
- What is his or her success rate?
- Is the facility capable of handling any of the above complications if they were to occur?
- Who performs the anesthesia, a physician or nurse anesthetist? If it is a nurse anesthetist, is an anesthesiologist supervising or providing backup?
- What is the overall infection rate at the facility?
- What is the surgeon's infection rate for this procedure?

In summary, although the evidence shows that many patients will improve without surgical intervention, microdiscectomy is a safe and effective procedure for those with symptomatic lumbar disc herniations that have failed conservative treatment. Prior to microdiscectomy, patients must commit to a lifestyle change and follow the pre- and post-operative instructions of their physician and therapist. Eliminate fear by asking appropriate questions and to speak to another patient with similar findings and similar demographics (age, sex, weight, etc). A positive attitude and knowledge of the procedure will go a long way in achieving a great surgical experience.

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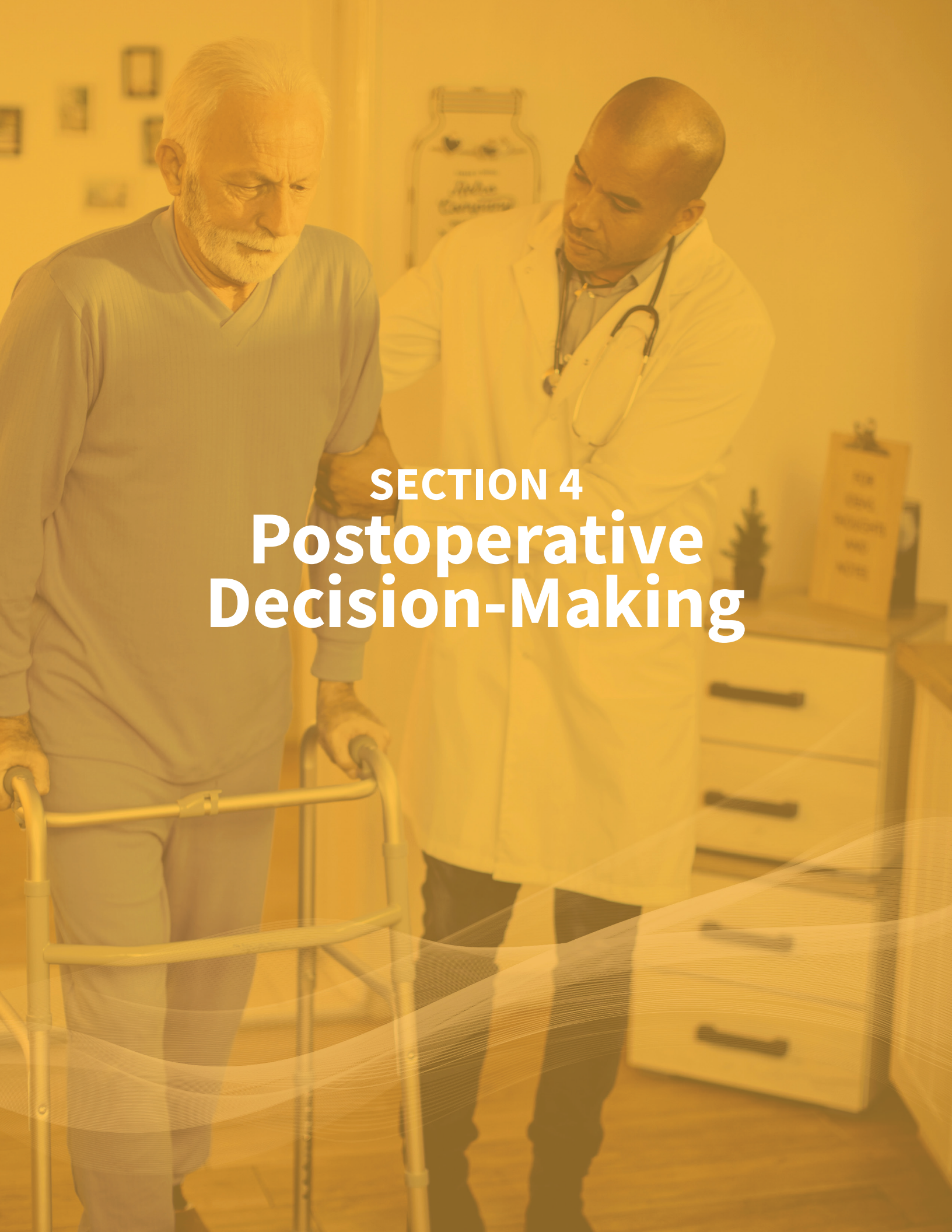

SECTION 4

# Postoperative Decision-Making

# WHEN CAN I GO BACK TO WORK?

**Sharad Rajpal, MD**
*Centura Spine and Neurological Associates*

One of the most common questions from patients preparing for back surgery is, "when can I expect to return to work?" Most published postoperative restrictions are based upon theoretical risks to patients and on surgeon opinions with no consensus on the 'right time' to return to work.[1-2] Although there are general guidelines for surgeons and patients, many factors need to be considered when making these recommendations, including a patient's occupation, age, overall medical health, and baseline functional ability. The spinal condition being addressed as well as the complexity and length of the surgery being performed must also be considered. To help provide return to work expectations following lumbar spine surgery, low back surgeries are simplified to 2 broad categories: non-instrumented lumbar spine surgeries (NILSS) and instrumented lumbar spine surgeries (ILSS). For these 2 surgical categories, work activities are separated into:

1. light duties (such as clerical work)
2. medium to moderate duties (such as a nurse or truck/fork-lift driver)
3. heavy duty labor (such as construction and bricklaying)

## NON-INSTRUMENTED LUMBAR SPINE SURGERY (NILSS)

Example surgeries in this category include microdiscectomies and laminectomy/decompressions. These surgeries are often performed through small incisions with short operating times and minimal blood loss, allowing most patients to be discharged home the same day. Patients can generally expect to resume light duty work activities around 2-4 weeks. More physical jobs with moderate work duties may have to wait a little longer, such as 4-6 weeks. Patients that need to perform more heavy duties may expect to return to work around 8 weeks, but this may be delayed to 12 weeks if surgery involves multiple spinal levels. Physical activities are then slowly increased with no limitations and a full return to work activities around 12-14 weeks from surgery.

## INSTRUMENTED LUMBAR SPINE SURGERY (ILSS)

Example surgeries in this category include the placement of hardware to "fuse" spinal segments. These surgeries are generally performed through a large open incision, or

several smaller minimally invasive incisions. Compared to NILSS, ILSSs are often longer, more complex, and require hardware placement (such as screws and grafts) to promote the bones to grow together. Depending on the type and extent of surgery (number of levels, etc.), some patients may go home the same day while others may require admission to the hospital for a few days. Recovery from ILSS is typically longer and more extensive than NILSS. For single level surgeries, patients can generally expect to resume light duty work activities around 2-4 weeks, with return to work for moderate duties around 6-8 weeks and 12 weeks for more heavier work duties. When patients undergo multi-level ILSS, the timeline for all work duties may be delayed to roughly 6 weeks for light duties, 8 weeks for medium duties, and 12-14 weeks for heavier labor duties. Similar to NILSS, patients can then expect to continue increasing their activities after 12-14 weeks.

Many patients are dependent on their income and may be eager to return to work in a shorter time frame than may be deemed reasonable by their surgeon[1]. It is important to remember that each patient is unique, thus any and all guidelines must be tailored to the individual patient's goals and postoperative pain levels. It is recommended to have an open discussion about returning to work expectations before surgery to avoid surprises or misunderstandings while ensuring safety.

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# SPORTS AFTER NECK SURGERY: HOW TO APPROACH THE ELITE ATHLETE

**Jacqueline E. Inglis, BA**
*Northwestern University Feinberg School of Medicine*

**Wellington K. Hsu, MD**
*Northwestern University Feinberg School of Medicine*

## BACKGROUND

One of the main concerns for an elite athlete is return to play (RTP) following spinal surgery. There are currently no evidence-based standardized guidelines, therefore these decisions are largely reliant on expert opinion and patient factors. There has been an evolution of management and treatment for cervical (neck) disc herniations in the elite athlete, especially those in collision sports, such as American football and rugby. Major factors guiding physician counseling include clinical recovery, patient goals, radiologic imaging, and historical data on successful RTP.

## 4-PRONGED APPROACH

At our institution, we employ a four-pronged approach to evaluating the elite athlete with a cervical disc herniation:

1. clinical presentation
2. imaging parameters
3. physical examination
4. sport played

If a player fails conservative management of their neck injury, such as therapy, rest, time, activity modification, and medications, then two common surgical options include: anterior cervical discectomy and fusion (ACDF) and posterior foraminotomy (nerve decompression).[1-2]

## AFTER SURGERY

Clinical indicators for RTP after surgery are still under debate, but are applied similarly to both procedures.[1,3]

**The following preclude a player from RTP:**

- persistent neurological deficits (weakness/dense numbness)
- spinal canal stenosis
- fusions involving the upper cervical spine (C1-2, C2-3)
- greater than three spinal level fusions

**Relative contraindications include:**

- fusion of two cervical levels
- asymptomatic fusion failures

**Athletes that meet the following criteria are generally cleared to play:**

- adequate fusion
- spinal stability
- full ROM
- lack of neurological deficits
- controlled pain

## OTHER CONSIDERATIONS

Another important consideration from the patient perspective is the risk of reinjury. Collision sports, such as American football and rugby, are associated with a greater relative risk of hyperextension and compression injuries to the spine thereby increasing chances of reinjury and traumatic stenosis. Lastly, social factors and career longevity goals are important factors in shared decision-making between physician and patient.[3]

## IMAGING PARAMETERS

The use of radiologic imaging parameters can be used as an objective measure for recovery. The Torg-Pavlov ratio compares the spinal canal width to the vertebral body width on MRI to determine the degree of stenosis (narrowing of the space for the spinal cord). There is still debate about the threshold value of the Torg-Pavlov ratio when it comes to return to sport, but in general RTP is not recommended if the ratio is indicative of stenosis associated with spinal cord injury.[1,4] Other imaging parameters include spinal cord and spinal canal diameters as predictors of cord injury and stenosis. MRI can reveal persistent edema in and around the spinal cord, however there is debate whether this should preclude an athlete from returning to play as some players have demonstrated successful RTP while others are advised to retire from sport. Use of these imaging parameters can help gauge successful recovery and give an athlete a better understanding of the feasibility of returning to a demanding level of sport.[1-2]

## RESEARCH

In a retrospective study following football players treated with a single level ACDF, 72% of NFL players returned to play for an average of 2.8 years as opposed to players treated nonoperatively, who returned to play for an average of 1.5 years.[5] A similar study found that 71% of NFL players were able to return to play 2-12 months after ACDF for an average of six months.[6] Rugby players appeared to have slightly more success, with 76% of rugby players returning to sport after ACDF.[7] There are discrepancies in outcomes when comparing ACDF to posterior decompression without fusion. Some studies report a greater frequency in return to play with quicker recovery but a greater chance of reoperation after decompression alone and others find no significant difference between decompression and ACDF in terms of RTP.[8]

## BOTTOM LINE

Ultimately, the main consensus is that much is still unknown about RTP after surgical interventions for the elite athlete. Currently, the best guides are clinical recovery of the athlete, imaging indicators, and evidence from previous athletes. When counseling a patient, all of these factors must be taken into account to provide the best picture on timing and successful return to play. Moving forward, additional studies, especially in relation to imaging and athlete success, may provide more defined guidelines for safe RTP.

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