

Improve your quality of life

An introduction to

SCOLIOSIS





Dear reader,

Medacta International is pleased to provide you basic guidelines to help you and your family gain the best possible understanding of this pathology.

Please consider this booklet as only a resource. If you need additional information please ask your doctor.

Always follow your surgeon's instructions, even when they differ from those outlined in this booklet.



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This brochure has been produced to help you to feel comfortable and safe about your operation. It addresses questions you may have about the surgery and post-operative recovery.





INTRODUCTION

The Spine, also known as the backbone or vertebral column, consists of 33 interlocking bones positioned on top of each other. It is made up of 24 separate bones interspaced with the "intervertebral discs", with the sacrum (5 fused bones) and the coccyx (4 fused bones) at the base.

The spine is a complex combination of interconnected bones, tendons, muscles, ligaments and nerves, any of which can become injured, misaligned or damaged leading to dysfunction.

The spine provides the main structural support of the body allowing mobility, the ability to walk upright, and it gives protection to the neurological elements (spinal cord and nerve roots) underlying and surrounding the bony structures.

Dysfunction specifically affecting the neurological elements (spinal cord or nerve roots) can result in sensitivity changes, muscle weakness or pain in the regions of the body supplied by the nerves. This can have far-reaching effects on a person's activity levels and general well-being.

Surgery may not be the only course of action as there are also a number of non-surgical treatments available. Discuss your options with your doctor to determine the best course of action for you.



1. ANATOMY OF THE SPINE

The spine is one of the most important structures in the human body. It supports much of the body weight, provides points of attachment for muscles and ligaments, and protects the spinal cord, which carries information from the brain to the rest of the body.

A healthy spine is strong yet flexible, allowing for a wide range of movements. It appears straight if viewed from behind and curved from the side. To understand scoliosis, you must first understand what a healthy spine looks like.

The spine is made up of vertebrae and is divided into five distinct regions:

- The **cervical spine** is your neck. It is composed of 7 vertebrae (C1-C7) and gives you the most motion.
- The **thoracic spine** is your mid-back. It is very stiff and composed of 12 vertebrae (T1-T12) larger than the cervical vertebrae and smaller than the lumbar vertebrae.
- The **lumbar spine** is your lower back. It contains 5 of the vertebrae, is the largest and strongest, and carries most of the body weight. It allows motion, especially bending and rotation.
- The **sacrum** consists of 5 fused vertebrae, it connects with the pelvis.
- The **coccyx** is made of 4 fused bones.

The vertebrae are separated by intervertebral discs, which act as shock absorbers to protect the vertebrae and allow spinal rotation and bending. Each disc consists of two parts:

- Annulus fibrosis, a tough outer fibrous ring
- Nucleus pulposus, a soft gelatinous center



LATERAL VIEW (SIDE) **POSTERIOR VIEW (BACK) POSTERIOR ANTERIOR** ATLAS (C7) AXIS (C7) **CERVICAL CERVICAL CURVE** 7 Vertebrae (LORDOTIC) **C7** T1 **TRANSVERSE PROCESS SPINOUS PROCESS VERTEBRAL BODY THORACIC THORACIC CURVE** 12 Vertebrae (KYPHOTIC) **INTERVERTEBRAL DISC** T12 L1 -**INTERVERTEBRAL LUMBAR LUMBAR FORAMEN** 5 Vertebrae **CURVE** (LORDOTIC) **PEDICLE** L5 **SACRAL CURVE SACRUM** COCCYX LAMINA **INTERVERTEBRAL DISC VERTEBRA** PEDICLE -



2. WHAT IS SCOLIOSIS

Everyone's spine has natural curves. Scoliosis is an abnormal rotation in addition to a lateral curvature in the normally straight vertical line of the spine. Patients with scoliosis could have curves that look more like a "C" (one curve) or an "S" (two curves). According to age of the patient, scoliosis could be **Pediatric Scoliosis** or **Adult Scoliosis**.



2.1 What are the causes of scoliosis

Scoliosis affects less than 1 percent of the world population¹, **mostly children** between the ages of 10-16 years.

Adult scoliosis is an entirely different condition, with different causes and treatment goals. In the elderly, the incidence can be as high as 68.6%. The most common causes include:

Adolescent Scoliosis of the Adult (ASA)

It is in essence, a continuation of adolescent idiopathic scoliosis. Sometimes a spine curvature of an idiopathic nature that began during teenage years may progress during adult life. Curves may increase in size 0.5° to 2° per year. It occurs in the thoracic (upper) and lumbar (lower) spine, with the same basic appearance as that in teenagers, such as shoulder asymmetry, a rib hump, or a prominence of the lower back on the side of the curvature.

Adult Degenerative Scoliosis

Also known as de novo (new) scoliosis. This type of scoliosis begins in the adult patient due to degeneration of the discs, arthritis of the facet joints and collapse and wedging of the disc spaces. It is typically seen in the lumbar spine (lower back), and usually accompanied by straightening of the spine from the side view (loss of lumbar lordosis).





2.2 Adult scoliosis symptoms

Both types of adult scoliosis can progress over time. If the curves reach 30 to 40 degrees, the deformity may be noticed by a hump or prominence in the area of the spine that is involved. Adults may have more symptoms than teens because of degeneration in discs and joints leading to narrowing of the openings for the spinal cord and nerves (spinal stenosis).

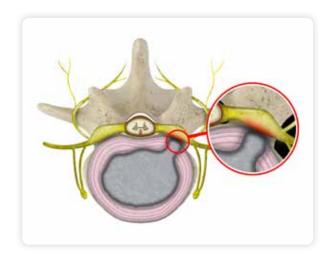
Adult patients may have a variety of symptoms, which can lead to gradual loss of function:

- Low back pain and stiffness are the 2 most common symptoms²
- Numbness, cramping, and shooting pain in the legs due to pinched nerves
- Loss of sagittal balance which can cause muscle fatigue

LOW BACK PAIN AND STIFFNESS



NUMBNESS, CRAMPING, AND SHOOTING PAIN



LOSS OF SAGITTAL BALANCE





2.3 Diagnosis

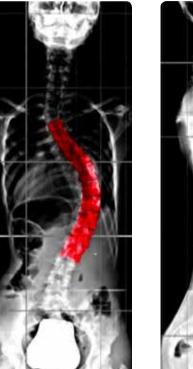
Any medical diagnosis usually commences with a thorough discussion of the medical history followed by a physical examination. In the case of scoliosis, your doctor will look at the spine and examine for any signs of scoliosis. You may be referred to have a series of X-rays, MRI or CT scans.

A **CT** or "**Computed Tomography**" scan, otherwise known as a CAT scan, uses X-Rays to produce cross-sectional images of the structures inside your body. During the scan, the machine spins around the body and sends the images to a computer monitor. A radiologist reviews the images and prepares a report for your doctor. A CT scan takes the images from multiple angles to build the cross-sectional image. This allows certain structures to be seen more accurately than they would be on a standard X-Ray.

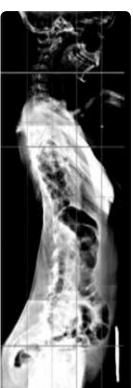
X-ray may be taken in order to evaluate any tilt or rotation of the vertebrae causing curvature. This allows the healthcare professional to confirm the diagnosis and monitor the degree and severity of the curve.

Magnetic resonance imaging (MRI) study of the spine is rarely used for patients experiencing minimal symptoms with adult idiopathic scoliosis. An MRI is usually ordered if you have leg pain, your physician finds some subtle neurologic abnormalities on physical examination, if you have significant pain or an "atypical" curve pattern.

POSTERIOR VIEW (back)



LATERAL VIEW (side)



CASE DESCRIPTION

- Structural 60° thoracic curve
- Non-structural high thoracic and lumbar curves
- Thoracic lordosis
- Classification Lenke 1A-type deformity
- Fusion from T5 to L3
- Structural curves are fixed, nonflexible, and fail to correct with bending
- Non-structural curves are not fixed but flexible and readily corrected with bending.



3. TREATMENT OPTIONS

In 90 percent of cases, scoliotic curves are mild and do not require active treatment³. Non-operative treatment is preferred, including periodic observation, pain relievers and physical therapy. The most important factors to determine the treatment are:

- Severity and the location of the curve
- Age, gender and physical maturity
- Associated symptoms

It is very important to monitor curves in adolescent patient, to prevent the progression of the pathology. In adolescent with moderate curves, **bracing** could be an appropriate treatment option to prevent increases in spinal deformity. Your doctor will show you the type that best meets your needs and will instruct you on how to put it on and take it off.

3.1 Surgical treatment

Surgical treatment is indicated for patients in whom the conservative approach has failed. It may be based on the following criteria:

- Scoliotic curve greater than 50°3
- Unbearable back pain
- Leg pain and neurologic deficit
- Muscle fatigue caused by spinal imbalance
- Curve progression
- Difficulty breathing

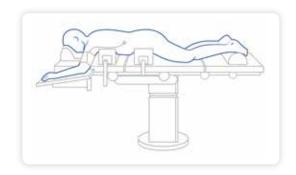
The goal of surgical treatment is to obtain curve correction and to prevent curve progression by fusing the spine at the optimum degree of safe correction of the deformity. This is generally achieved by placing metal implants into the spine that are then connected to rods, which correct the spine curvature and hold it in the corrected position until fusion of the spine elements together.



3.2 What happens during the surgery?

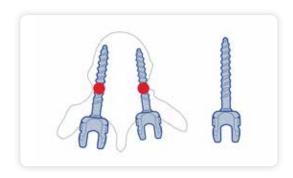
APPROACH

The patient is comfortably positioned in prone position over the operating table. A midline incision is performed and the soft tissue is gently moved laterally to expose the bony structures that need to be treated.



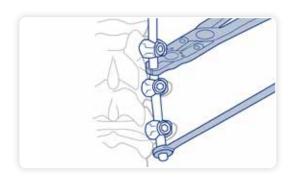
IMPLANT

The pedicle screws are implanted into the vertebrae. The appropriate rods are selected and contoured in order to match patient's deformity. The rods are securely locked over the screws. Hooks may also be used in conjunction with screws for enhanced stability, and are placed around the pedicle or around the part of the bone called the lamina.



CORRECTION

With dedicated instruments the surgeon corrects the deformity and restores the physiological spine curvature.



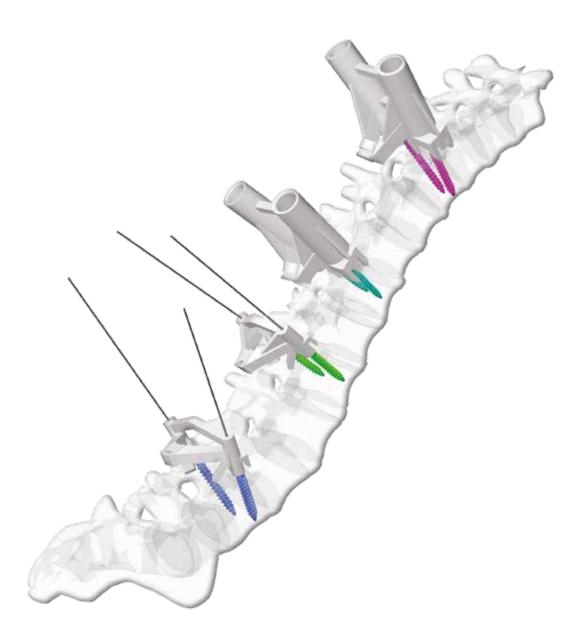




3.3 Why would my doctor choose a MySpine surgery

MySpine is a patient-matched, 3D printed technology tailored to the patient's anatomy allowing to simplify pedicle screw placement. MySpine is a validated technology supported by scientific data. [1,2,3,4,5,6] The main patient benefits of MySpine are:

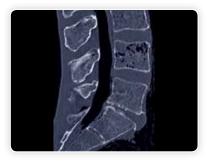
- **Accuracy** of pedicle screw position^[2]
- Patient-matched technology allowing for surgical technique customisation
- Low dose radiation protocol benefits the patients in comparison to C-Arm or O-Arm navigational technologies: up to 30 times less irradiation!^[1]
- Potential **reduction** in the post-operative morbidity and **shortening** of the length of hospital stay^[4]



3.4 The MySpine Advantage

MySpine is a surgical instrument designed to accurately fit your vertebrae.

How does it work?



OBTAIN AN IMAGE OF YOUR SPINE

The surgeon will ask you to have a CT scan of your vertebral column. Medacta developed a specific Low Dose CT protocol to ensure a safe image acquisition. In fact you will receive a very similar amount of irradiation to only a single spine X-ray!



REPLICATION OF YOUR SPINE

Using images of your spine, Medacta will create a plastic 3D model for each of the vertebra to be treated, in order to allow the physician to select the best implant position and size for you.



CREATION OF MYSPINE

Using the model of your vertebrae and a dedicated planning software, your surgeon designs your personalized surgical instruments.



PREPARATION OF SURGERY

Prior to the surgery, your surgeon will receive the MySpine instruments and the plastic replica of your vertebrae. The bone model and the screw placement guides will be analyzed to accurately prepare for your spine operation.



THE DAY OF SURGERY

The MySpine guides will help positioning the pedicle screws very accurately according to pre-operative plan.



4. PREPARATION

Depending on your condition, your recovery will be tailored to meet your needs. Your physician will determine the appropriate length of your hospital stay. Your recovery will continue at home or in a rehabilitation center.

It is important for you to make a commitment to follow your doctor's instructions so you can benefit the most from surgery. Plan for assistance in your home after surgery. Consider your need for assistance in meal preparation, cleaning and other home activities.

4.1 What To Do Before Surgery

Four weeks before surgery

Quitting smoking is the single best thing you can do to have your wound heal, bone fuse and reduce risks of infection.

Ten days before surgery

According to your conditions, you might be asked to discontinue arthritis medication. Aspirin, aspirin-containing medications and antiplatelet drugs should be discussed with your physician since many of these drugs can cause interactions with others in preparation for surgery.

The night before surgery

Unless otherwise directed by your doctor DO NOT eat or drink anything after midnight. This includes no water, gum, candies and do not smoke. Brush your teeth. Be sure to have a bowel movement prior to the surgery, using a suppository or laxative if necessary.

The morning of surgery

Clean your body. Do not apply lotions or powders to your surgical area or legs. Take only the medications directed by your physician. Take them with the smallest amount of water needed to swallow the medication (only a sip).



4.2 Prepare Your Home

Arrange for help

- You will not be able to drive for a certain amount of time after your surgery.
- Make arrangements to have someone stay with you, if needed.
- Have family or friends available to assist you once you're home.

Reduce your risk for a fall

- Remove any throw rugs.
- Tack down any loose carpeting so walking will be safer.
- Look around the room for other hazards and remove them.
- Wear shoes with non-skid soles (not house slippers).
- Make sure you have a supportive, comfortable chair in your home.

4.3 What to bring to the hospital

- List of medications that you are taking, amount you take, and how frequently you take them (do not bring all your medications)
- DO BRING migraine medications if you are prone to migraines
- DO BRING inhalers if you use them
- Glasses, hearing aides, dentures, toiletries and slippers
- Orthoses
- · Insurance information and an emergency telephone number
- Wear comfortable clothes to the hospital you will wear these home





5. IN THE HOSPITAL

The following staff members may be involved in your care:

Neurosurgeon or orthopedic surgeon

- Performs surgery and directs your care
- Visits you on rounds in the hospital
- Evaluates you at follow-up appointments at the office

Nursing staff

- Coordinates and provides patient care in the hospital
- Shares information about your condition to the healthcare team
- Helps you plan for the move to your home or extended care facility
- Is available to answer your questions during your hospital stay

Physical therapist

- Evaluates your physical capabilities
- Instructs and assists you with a rehabilitation program
- Provides instructions for home activity
- Identifies possible home needs

Your responsibility as a patient

- Ask questions about anything you do not understand
- Let the staff know about any problems
- Come with an up-to-date and correct list of your home medications
- Carefully follow the directions given by the medical team both before and after discharge from the hospital
- Plan for help at home after surgery



6. AFTER THE SURGERY

Recovery

You will wake up after your procedure in the post-operative recovery room. This is the area of the hospital where your condition is monitored and your vital signs are observed. Generally, a patient will only remain in the post-operative recovery room for a few hours. From there, according to your conditions, you will be transferred to your hospital room on the ward.

Some pain around the incision site is normal, but discuss how you are feeling with your medical team.

Release from Hospital

The hospital discharge depends on the extent of your operation and how your recovery is progressing. Your doctor will decide on the best post-operative course of action for you.

Rehabilitation

During your recovery phase in the hospital you may be asked to carefully sit, stand or walk under supervision. You may also be required to use a brace to assist your spine with the fusion process. Once you have been released from the hospital, it is important to adhere to the instructions given by your medical team. You may need to limit certain activities or undergo some prescribed physical therapy. Your doctor will discuss any required medications you require as well as give you instructions on wound care, activities and exercise.

Don't Forget

- A healthy diet and regular exercise are important.
- Schedule regular check-ups.
- Contact your surgeon if you have any concerns about your Spine.





7. FREQUENTLY ASKED QUESTIONS

Can spinal deformities be prevented?

Currently, there is very little that can be done to prevent spinal deformities.

Does scoliosis run in families?

Yes. Idiopathic Adolescent Scoliosis has a genetic component and up to one third of patients have a family history of spinal deformity. At present, researchers are unsure which gene causes scoliosis.

What causes scoliosis?

It depends on the type of deformity. If a specific cause is unknown, it is deemed "Idiopathic" (for example in Adolescent Idiopathic Scoliosis). Some forms of scoliosis however have a known source:

- Congenital scoliosis (abnormally formed vertebrae at birth)
- Neuromuscular scoliosis (nerves and muscles unable to maintain anatomical alignment eg.
 Cerebral Palsy, Muscular Dystrophy)
- Genetic conditions (such as Osteogenesis Imperfecta, Down's Syndrome)
- Anatomical changes due to age, trauma or disease

What does not cause scoliosis?

Lifestyle factors and habits are not responsible for creating a spinal deformity. Carrying heavy school bags, sporting activity, poor posture or minor leg length differences do not cause scoliosis.

What options do I have?

There are a number of solutions, surgical and non-surgical, to treat your disease. Ask your doctor what is the most suitable treatment based on your age, activity level and expectations.

Are there any risks for this kind of operation?

Any surgical procedure comes with risks. Serious complications are rare and your surgical team will do everything possible to avoid issues arising. However, the most serious potential risks include

- Paraplegia (Very rare 1 in 1,000 to 1 in 10,000 chance)
- Excessive blood loss
- Continued progression of the curve after surgery
- Failure of the spine to fuse
- Infection

Please consult your doctor for a complete list of indications, warnings, precautions, adverse effects, clinical results, and other important medical information that pertains to scoliosis surgery.

Is the procedure covered by insurance?

It is always best to check and confirm with your insurance plan provider in advance.

Is it possible to have an MRI scan after the implantation of metal devices in my body?

It depends of several factors including physical characteristics of the devices, body area where the implants are located and type of MRI equipment. Likely, the imaging may be however disturbed to some extent by the metallic implants.

Do the Spine implants activate the metal detectors at airports?

Sometimes this can happen but it depends on the sensitivity of the detectors at the points of control of the airport. All of Medacta's Spine implants are identified by a card called Implant Passport, provided by your surgeon after the operation. Always carry it with you and present it if necessary!





PHARMACOTHERAPY							

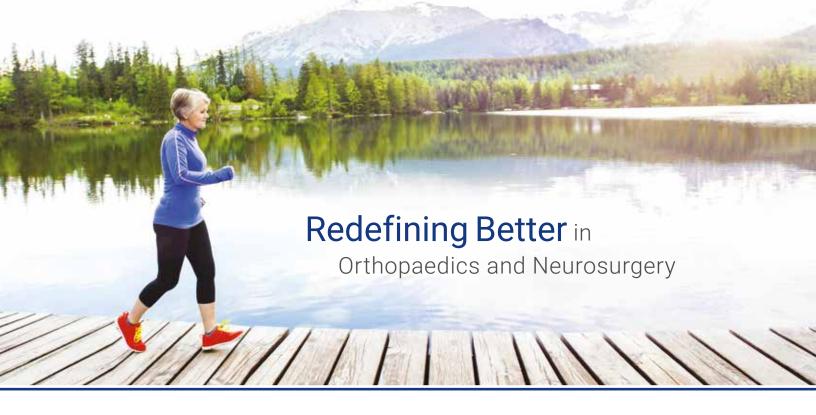
References:

^[1] Lamartina et al. Adolescent idiopathic scoliosis surgery with patient-specific screw placement-guide Eur Spine J. 2014 Dec;23(12). MySPINE VIDEO CASE / REDUCED DOSE RADIATION ^[2] TLamartina et al. Pedicle screw placement accuracy in thoracic and lumbar spinal surgery with a patient-matched targeting guide: a cadaveric study. Eur Spine J. 2015 Nov;24(7). MySPINE ACCURACY VS FREE HAND ^[3] Putzier et al. A New Navigational Tool for Pedicle Screw Placement in Patients with Severe scoliosis: A Pilot Study to Prove Feasibility, Accuracy, and Identify Operative Challenges. J Spinal Disord Tech. 2014 MySPINE PILOT STUDY ^[4] Landi et al. Spinal Neuronavigation and 3D-Printed Tubular Guide for Pedicle Screw Placement: A Really New Tool to Improve Safety and Accuracy of the Surgical Technique? J Spine 2015, 4:5 MySPINE ACCURACY VS GUIDED TECHNIQUE ^[5] Landi et al. 3D Printed Tubular Guides for Pedicle Screw Placement: The Answer for the Need of a Greater Accuracy in Spinal Stabilization. Orthop Muscular Syst 2015, 4:3 MySPINE ACCURACY / EASE OF USE ^[6] Accuracy of patient-specific template-guided vs. free-hand fluoroscopically controlled pedicle screw placement in the thoracic and lumbar spine: a randomized cadaveric study. Eur Spine J. 2016

PHYSIOTHERAPY							

Contraindications, Complications, Warnings and Precautions

All Spinal procedures come with a small risk of complications. Please speak with your doctor about the potential risks of your surgery as well as the common post-operative side-effects such as pain and discomfort.



For further information visit the website:

medacta.com





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