PATIENT INFORMATION



EARLY ONSET

SCOLIOSIS

INFORMATION ABOUT SCOLIOSIS, ITS SYMPTOMS, AND TREATMENT OPTIONS





Early Onset Scoliosis

Patient Information

This brochure will help you understand more about:

- Anatomy of the spine
- Scoliosis, its symptoms, and treatment options
- What to expect from surgery

The decision to receive medical treatment is individualized to the patient and the patient's symptoms. The information presented within this brochure may not apply to your condition, treatment or outcome, as surgical techniques vary and complications can occur. It is important to discuss the viability of treatment with your physician to decide which treatment option is right for you.

This brochure is intended to be an educational resource only and is not meant to be a warranty or to replace a conversation between a patient and their physician or member of their health care team. Please consult your physician for a complete list of indications, precautions, clinical results and other important medical information that pertains to surgical treatment.



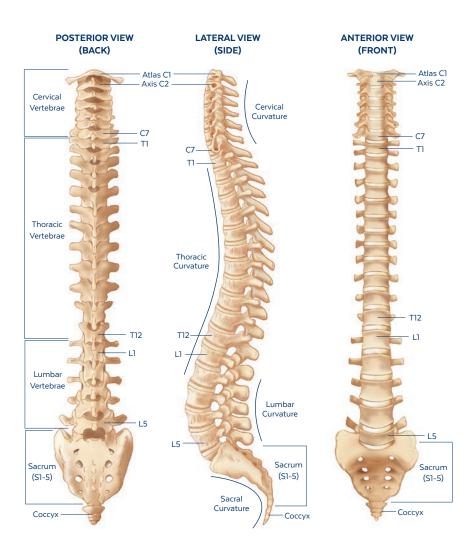
Table of Contents

- 4 Anatomy of the Spine
- 6 What Is Scoliosis?
- 7 What Is Early Onset Scoliosis (EOS)?
- 7 What Causes Scoliosis?
- 8 What Are the Symptoms of Scoliosis?
- 9 How Is Scoliosis Diagnosed?
- 10 General Treatment Options
- 11 EOS Surgical Treatment
- 14 Surgical Treatment
- 15 Contraindications and Adverse Effects
- 17 Scoliosis: Fast Facts
- 18 Scoliosis Resources

Anatomy of the Spine

The spine is one of the most important structures in the human body. It supports much of the body's weight and protects the spinal cord, which carries information from the brain to the rest of the body. The spine is strong yet flexible, allowing for a wide range of movements.

To understand scoliosis, you must first understand what a healthy spine looks like.



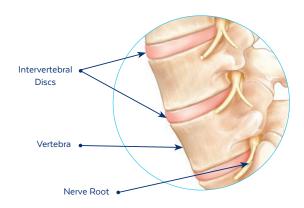
The spine is made up of vertebrae (bones) and is divided into three distinct regions:

- Cervical spine: The cervical spine is your neck. It starts at the base of your skull and contains seven vertebrae.
- ▶ Thoracic spine: The thoracic spine is your mid-back. It contains 12 vertebrae that connect to the ribs and sternum, making this portion of the spine very stable.
- Lumbar spine: The lumbar spine is your lower back. It contains five vertebrae, the largest and strongest, and carries most of your body weight.

Below the lumbar spine is the sacrum, which is comprised of five fused vertebrae. At the end of the spine is the coccyx or the tailbone.

From behind, the healthy spine appears to be straight. However, when viewed from the side, the spine is naturally curved inward and outward, which allows the spine to support more weight.

The vertebrae bear the weight of the upper body and provide points of attachment for muscles and ligaments. They also protect the spinal canal (cavity that runs through each of the vertebrae and contains the spinal cord) and provide exit points for spinal nerves. Each individual vertebra is separated by intervertebral discs, which act as cushions or shock absorbers between the vertebrae.



What Is Scoliosis?

Scoliosis is a sideways curvature of the spine. When a healthy spine is viewed from the back, it appears to be straight. However, patients with scoliosis have curvatures that look like a "C" (one curve) or an "S" (two curves) when viewed on an X-ray.

There is ongoing research into the potential causes of scoliosis, including genetics, soft tissue disorders, and abnormalities in the central nervous system.

The curve of the spine is measured in degrees, referred to as a Cobb angle. When the Cobb angle is greater than 10°, the patient is considered to have scoliosis.



What Is Early Onset Scoliosis (EOS)?

EOS affects skeletally immature patients less than 10 years of age. Patients with EOS are still undergoing development, which can place them at risk for progression of the curve. If EOS progresses to a severe state, the spine can crowd the space within the chest cavity, and cause thoracic insufficiency syndrome (TIS), where the chest cavity (thorax) cannot support normal breathing or lung growth. Treatment for EOS should be sought in a timely manner to prevent further progression.

What Causes Scoliosis?

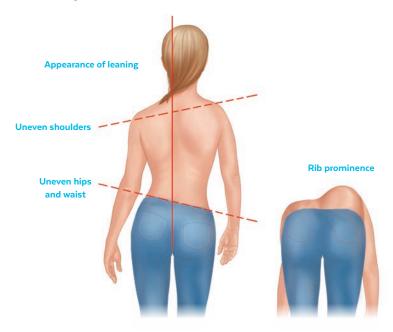
Scoliosis can arise from a number of underlying conditions. Doctors do not know what causes the most common type of scoliosis, idiopathic, meaning "of unknown origin." Idiopathic scoliosis does appear to involve hereditary factors, because the disorder has been shown to run in families. Other types of scoliosis may be caused by:

- Neuromuscular conditions, such as cerebral palsy or muscular dystrophy
- Birth defects affecting the development of the bones of the spine
- Injuries to or infections of the spine, and underlying syndromes

What Are the Symptoms of Scoliosis?

The most common signs of scoliosis include:

- Uneven shoulders and/or shoulder blades
- Uneven hips and waist
- Appearance of leaning
- ▶ Head is not centered over the body
- Rib prominence on one side that is most noticeable when bending forward



Those with moderate to severe scoliosis may experience one or more of the following symptoms and complications:

- Reduced range of motion
- Back pain
- More commonly in severe early onset scoliosis, trouble breathing and cardiovascular issues from the rib cage pressing on the lungs and heart

How Is Scoliosis Diagnosed?

The diagnosis typically begins with a complete history followed by a thorough physical examination. A healthcare professional examines the spine and looks for any signs of scoliosis.

X-rays may be taken in order to evaluate any tilt or rotation of the vertebrae causing a curvature. X-rays allow the doctor to confirm the diagnosis, monitor the degree and severity of the curve, and assess the patient's skeletal maturity.



Posterior view (back)



Lateral view (side)

General Treatment Options

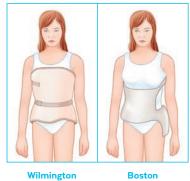
Treating scoliosis must take into account the severity of the curve, the age and state of physical maturity, and the location of the curve. Treatment options range from observation, bracing and casting, to surgery.

Observation

Observation is appropriate for mild size curves that have a low risk of progression when the patient is still growing, or for moderate size curves when growth is complete. Your doctor will make recommendations regarding the need for X-rays and how often to be seen based on the progression of the curve.

Bracing

Bracing is appropriate for moderate size curves in growing children to prevent further progression of the curve while growth of the spine remains. The goal of bracing is not to correct the curve, but to prevent further progression into a more severe curve. Your doctor will advise you on which brace is most effective



Brace

Brace

in managing the curve. There are two types of bracing that are often recommended: the Wilmington Brace and the Boston Brace.

Surgical Treatment

Surgical treatment is reserved for moderate to severe size curves. It may be recommended when the curve continues to progress and there is significant growth left in the spine, or brace treatment has failed.

The surgical treatment goals for EOS are:

- Controlling curve progression,
- Preserving spinal growth and general spinal mobility, and
- Maximizing lung function.

^{1.} Scoliosis Research Society 2019. Available online at: http://www.srs.org.

EOS Surgical Treatment

The doctor will determine when surgical intervention is an option. This may depend on:

- The size of the curvature
- ▶ The patient's remaining growth

Procedures to treat EOS include:

- Guided growth treatment
- Distraction-based treatment
- Definitive fusion

Guided Growth Treatment

In guided growth techniques, during a surgical procedure screws or hooks are placed in the top, middle, and bottom on both sides of the spine and connected by rods. The rods slide within the anchors while guiding the spine into a straighter position as the patient grows.

Traditional Distraction-Based Treatment

When undergoing a traditional distraction-based implant procedure, an initial surgery is performed to implant a growing rod(s) on the spine to gain control over the deformity. Following the initial surgery, the doctor will perform distraction or rod lengthening procedures through a small incision while the patient is under general anesthesia to straighten and lengthen the spine as the child grows. On average, this planned surgery occurs twice a year.

Distraction-Based Treatment by Globus

Globus' MARVEL® Growing Rod System uses growing rods implanted similarly to traditional approaches, but with subsequent minimally invasive distractions to minimize soft tissue disruption. The implanted growing rods are mechanically expanded using a small driver to provide reliable distraction and allow for continued growth during treatment.



Following guided growth or distraction-based treatment, the doctor will decide when the patient's bones have matured enough to discuss options for future treatment. Options may include a final surgery to correct remaining scoliosis.

Definitive Fusion

For EOS patients, a definitive fusion surgical procedure occurs once growth is complete. In a definitive fusion procedure, fixation systems (metal rods and screws) are implanted into both sides of the patient's spine to stabilize the curve. Bone graft may be used to help provide the necessary environment for the body to grow new bone. Over time, the operated segment of the spine heals into a solid block of fused bone that cannot bend.



Surgical Treatment

What Can I Expect with My Recovery?

Surgical treatment for scoliosis may help you return to normal activities. Although recovery time varies between patients, following the initial surgery, many are in the hospital for 1-2 weeks and out of school for 2-6 weeks. They may return to activities as soon as 2-6 months after surgery, or up to 9 months following the procedure. Subsequent distraction procedures will also involve a recovery period, but it will generally be less than the initial procedure.

It is the surgeon's goal for the patient to return to his/her preoperative activities. A positive attitude, reasonable expectations, and compliance with your doctor's post-surgical instructions may all contribute to a satisfactory outcome.



Contraindications and Adverse Effects

You may be contraindicated (not suitable) for these devices if you have an infection, congenital abnormality, tumors, inadequate pedicles, tissue deficits, vertebral fractures, certain allergies, rheumatoid arthritis, osteopenia, osteoporosis, or cancer, or are obese, pregnant, mentally ill, or diabetic. In addition, a patient whose mental or physical impairment places undue stresses on the implant during healing may be at a higher risk of implant failure.

As with any surgical procedure, complications or adverse effects may occur following the placement of these devices. These can include, but are not limited to, early or late implant bending, breakage, device fracture or failure, loss of fixation, subsidence, loosening, movement/migration, reduced spinal growth, abnormal sensations, decrease in bone density or bone fracture, and allergic reaction to implant material.

Other adverse effects that may be associated with any spinal surgical procedure include non-union or delayed union, pain, secondary surgery, bleeding, infection, spinal cord and/or nerve damage, incisional complication, scar formation, blood vessel damage, organ damage, muscle impairment, cardiovascular system compromise, respiratory problems, change in spinal curvature, complications due to bone grafting, reactions to anesthesia, restriction of activities, impotence, sexual dysfunction, paralysis, and death.

If you experience any of the above adverse effects, please contact a health professional. This list does not include all possible contraindications and adverse effects. Please consult with your surgeon for additional information on this topic and how it applies to your particular medical condition. If you experience a serious adverse effect with your implant, please report the incident to your local health authority and to Globus Medical. Some health authorities are listed below for convenience.

Region	Authority	Website
All	Globus Medical	https://www.globusmedical.com/ international/about/contact/
Australia	Therapeutic Goods Administration (TGA)	https://www.tga.gov.au/
New Zealand	Medicines and Medical Device Safety Authority (MEDSAFE)	https://www.medsafe.govt.nz/
United Kingdom	Medicines and Healthcare Products Regulatory Agency (MHRA)	https://www.gov.uk/government/ organisations/medicines-and-healthcare- products-regulatory-agency
Other	Report to your local health authority per local guidelines	

Scoliosis: Fast Facts

- · Scoliosis is the most common deformity of the spine.1
- Scoliosis causes the spine to abnormally curve sideways, into an "S" or "C" shape.¹
- Scoliosis affects 2%-3% of the population.²
- The four main causes of pediatric scoliosis are idiopathic, syndromic, congenital, and neuromuscular.
- Severe EOS may cause thoracic insufficiency syndrome (TIS), where the chest cavity (thorax) cannot support normal breathing or lung growth.¹
- Although girls and boys are diagnosed with scoliosis in equal numbers, girls are eight times more likely to have a curve that progresses and requires treatment.²
- Common signs and symptoms include uneven shoulders, ribs, hips or waist, one shoulder blade more prominent than the other, rib prominence, or one arm hanging lower than the other.¹
- In 85% of cases, the cause of scoliosis is unknown; this is called idiopathic scoliosis.²

^{1.} Scoliosis Research Society 2019. Available online at: http://www.srs.org.

National Scoliosis Foundation. Information and support. Cited 4 Nov 2019. Available online at: http://www.scoliosis.org/patient-support/.

Scoliosis Resources

AMERICAN ACADEMY OF ORTHOPEDIC SURGEONS (AAOS)

Address: 6300 North River Road, Rosemont, IL 60018

Phone: (847) 823-7186 Website: www.aaos.org

AMERICA ACADEMY OF PEDIATRICS (AAP)

Address: 141 Northwest Point Boulevard, Elk Grove Village, IL 60007

Phone: (847) 434-4000 Website: www.aap.org

AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS (AANS)

Address: 5550 Meadowbrook Drive, Rolling Meadows, IL 60008

Phone: (847) 378-0500 Website: www.aans.org

AMERICAN PHYSICAL THERAPY ASSOCIATION (APTA)

Address: 1111 North Fairfax Street, Alexandria, VA 22314

Phone: (703) 684-2782 Website: www.apta.org

CURVY GIRLS SCOLIOSIS

Website: www.curvygirlsscoliosis.com

INTERNATIONAL RESEARCH SOCIETY FOR SPINAL DEFORMITIES (IRSSD)

Address: The University of Liverpool, Sherrington Building, Ashton Street,

Liverpool L69 3GE UK Phone: 44 151 794 5502

Website: www.liv.ac.uk/ HumanAnatomy/phd/irssd

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES (NIAMS)

Address: 1 AMS Circle, Bethesda, MD 20892

Phone: (301) 495-4484 Website: www.niams.nih.gov

NATIONAL SCOLIOSIS FOUNDATION (NSF)

Address: 5 Cabot Place, Stoughton, MA 02072

Phone: (800) 673-6922 Website: www.scoliosis.org

NORTH AMERICAN SPINE SOCIETY (NASS)

Address: 22 Calendar Court, 2nd Floor, LaGrange, IL 60525

Phone: (877) 774-6337 Website: www.spine.org

PEDIATRIC ORTHOPAEDIC SOCIETY OF NORTH AMERICA (POSNA)

Address: 6300 North River Road, Suite 727, Rosemont, IL 60018

Phone: (847) 698-1692 Website: www.posna.org

SOCIETY ON SPINAL ORTHOPEDIC AND REHABILITATION TREATMENT (SOSORT)

Email: kotwicki@amp.edu.pl Website: www.sosort.org Phone: 44 151 794 5502

SCOLIOSIS RESEARCH SOCIETY (SRS)

Address: 555 East Wells Street, Suite 1100, Milwaukee, WI 53202

Phone: (414) 289-9107 Website: www.srs.org

THE GERMAN SOCIETY FOR ORTHOPAEDICS AND TRAUMA (DGOU)

Website: www.dgou.de/dgou/

THE GERMAN SPINE SOCIETY (DWG)

Website: www.dwg.org

THE SCOLIOSIS ASSOCIATION, INC.

Address: P.O. Box 811705, Boca Raton, FL 33481

Phone: (561) 994-4435

Website: www.scoliosi-assoc.org

About Globus Medical: Globus Medical, Inc. is a leading musculoskeletal implant company based in Audubon, PA. The company was founded in 2003 by an experienced team of professionals with a shared vision to create products that enable surgeons to promote healing in patients with musculoskeletal disorders.



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Customer Service: Phone: 1-866-GLOBUS1 (or 1-866-456-2871) Fax: 1-866-GLOBUS3 (or 1-866-456-2873)

