Medtronic

SHILLA™

Growth Guidance System

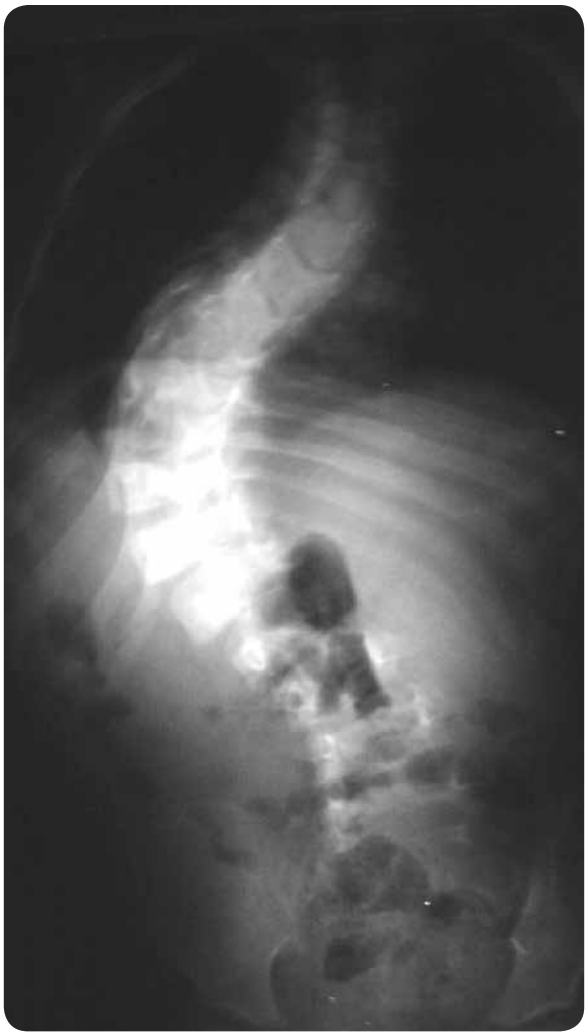
Product Information

Introduction

Early-onset spinal deformity is a term most appropriately applied to children under the age of 10 years. It can be characterized by severe, progressive, life-threatening early-onset spinal deformities, including early-onset scoliosis, which are associated with or at risk of thoracic insufficiency syndrome.

Early-onset scoliosis (EOS) is defined as a significant curvature of the spine that can occur in the pediatric population before the age of five and the scoliosis may be of many different etiologies.[1] Early onset scoliosis can have detrimental effects on the pulmonary development of the alveoli in the postnatal period and life-threatening cardiovascular and pulmonary sequelae can result in children with severe thoracic curvatures.[1-3] Therefore progressive spinal deformities can create significant health risks as well as cosmesis issues for the EOS patient. Hence, the management of pediatric scoliosis remains a complex problem of spinal deformity during the early years of growth and development.

Traditional treatment options for EOS have included observation, bracing, casting, and spinal fusion. Bracing is non-invasive and can preserve development growth and motion. However it has been shown to be moderately successful at preventing curve progression in curves less than 40°.[4] Serial casting is reported to be effective in mild infantile idiopathic scoliosis. For nonidiopathic scoliosis, the reported surgical rate was 53% after casting compared to 10% for idiopathic patients.[5,6] For young children, with progression of the deformity and failure of nonoperative measures, early surgical intervention may be indicated to prevent further deterioration in their health and level of physical activity. Instrumented spinal fusion is effective for preventing progression and correction of curves but fusion causes loss of motion and adversely impacts growth of spine height and development of the chest.[7-8] In order to overcome some of the concerns associated with fusing the spine to correct the deformity in the growing child, technologies have been developed to provide growth-sparing surgical options that would allow growth development and maintain spine mobility.



Radiographic image of a EOS patient.

Current fusionless or growth-sparing surgical interventions include distraction-based systems which require periodic rod lengthening procedures, with varying degrees of invasiveness, typically every 6-9 months. The complication rate for such procedures can be as high as 206%, with the complication rate increasing as the number of procedures increases.[3,9-10] Thus, there is a need for self-lengthening instrumentation to avoid repeated surgeries in this vulnerable population.

Summary of Indications

SHILLA™ Growth Guidance System is a new growth-sparing technology that helps provide deformity correction while allowing continued growth at the proximal and distal construct ends and helping to reduce the need for periodic distractions or lengthening procedures. SHILLA™ Growth Guidance System provides a unique non-locking set screw that allow the pedicle screws to slide along the rod axis during vertical growth.

The SHILLA ™ Growth Guidance System is indicated for skeletally immature patients less than 10 years of age with potential for additional spinal growth who require surgical treatment for correction and maintenance of the correction of severe, progressive, life-threatening early-onset spinal deformities, including early-onset scoliosis, which are associated with or at risk of thoracic insufficiency syndrome. The SHILLA ™ Growth Guidance System is intended to be removed after skeletal maturity.

SHILLA™ Fixed Angle Screw with Locking Set Screw

SHILLA™ Multi-Axial Screw with Non-Locking Set Screw

SHILLA™ Growth Guidance System Potential Benefits

- Helps allow for correction and stability with growth
- Helps allow for natural increase of trunk height (T1-S1)
- Helps allow for unimpeded development of thoracic cavity
- Helps maintain corrected alignment
- Designed to reduce the need for periodic distractions and lengthening surgical procedures

SHILLA™ Growth Guidance System Product Risks

It may be appropriate to consider the need for additional procedures prior to implantation of the SHILLA™ Growth Guidance System including preoperative halo traction or anterior spinal surgery.

Additional adjunctive surgical procedures may be required in conjunction with implantation of the SHILLA™ Growth Guidance System including but not limited to posterior spinal column osteotomy procedures (Ponte type, Smith Petersen type), pedicle based osteotomy procedures, vertebral body decancellation procedures, vertebral column resection procedures, thoracoplasty procedures, anterior spinal surgery, and iliac bone graft harvest procedures.

Clinical Evidence

SHILLA™ Growth Guidance System was studied in a retrospective, multicenter study comparing the SHILLA™ System to growing rod (GR) surgical intervention and posterior spinal fusions (PSF) for the surgical treatment of early-onset scoliosis.[11]

» 27 patient retrospective study

- 19 treated with the SHILLA™ Growth Guidance System
- 8 patients in two control groups
  - Growing Rods (n= 6)
  - Posterior Spinal Fusions (n=2)

» Patients followed an average of 3.86 years in the SHILLA™ System group, 3.64 years in the Growing Rod group and 4.57 years in the Fusion group.

- Majority of the patients had >2 years follow-up; 85% in SHILLA™ System group, 83% in Growing Rod group and 100% in Fusion group.

» One SHILLA™ System patient was converted to a Growing Rod construct and one Growing Rod patient was converted to SHILLA™ System. This data is not included in the patient tables.

» Because of the limited number of patients enrolled in the study, no statistical analysis was performed.

» Both the SHILLA™ System group and Growing Rod group included patients under the age of 5.

» SHILLA™ System patients had diagnoses of syndromic (36.8%) scoliosis, infantile idiopathic (26.3%) scoliosis, neuromuscular (26.3%) scoliosis and juvenile idiopathic (10.5%) scoliosis. In the Growing Rods control group patients had diagnoses of juvenile idiopathic (50.0%) scoliosis, infantile idiopathic (16.7%) scoliosis and syndromic (16.7%) scoliosis. The Fusion group consisted of a patient diagnosed with neuromuscular scoliosis and a patient diagnosed with congenital scoliosis.

» Major curves ranged from 42° to 115° in the SHILLA™ System group, 45° to 92° in the Growing Rods group and 62° to 71° in the Fusion group.

Demographics	SHILLA™ System	Growing Rod	Fusion
N	19	6	2
Age (yrs.) (range)	6.1 (2.0 – 9.9)	5.8 (2.8 – 8.5)	7.6 (7.5 – 7.7)
Weight (lbs.)	44.8	51.0	50.0
Sex (male/female)	7/12	2/4	1/1
Primary Diagnosis			
Congenital Scoliosis	0	0	1
Neuromuscular Scoliosis	5	0	1
Syndromic Scoliosis	7	1	0
Infantile Idiopathic	5	1	0
Juvenile Idiopathic	2	3	0
Mean Major Curve (Pre-op)	70.3°	68.3°	66.5°
Ambulatory Status (Pre-op)	15 (78.9%)	6 (100%)	1 (50%)

Radiographic Results

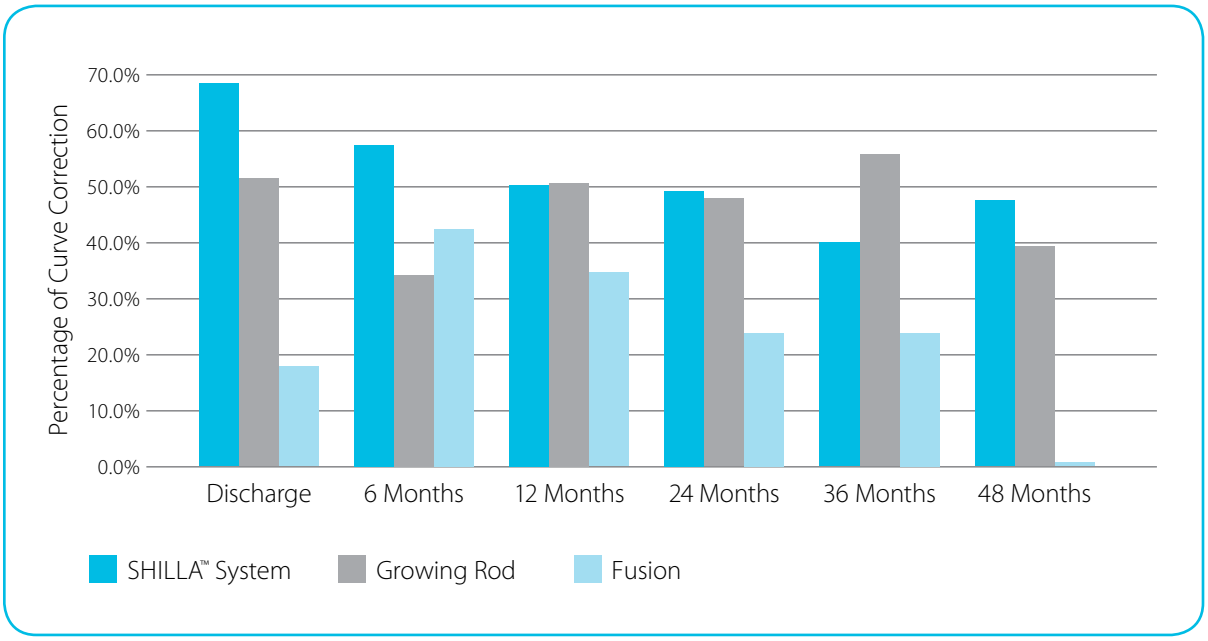
Curve correction and maintenance during growth was achieved with SHILLA™ Growth Guidance System.

As shown in the table, the accountability for patients with full radiographic data available for analysis decreased from 85% at discharge to 62.9% at 36 months postoperatively.

Summary of Curve Correction and Maintenance	SHILLA™ System	Growing Rod	Fusion
n (enrolled)	19	6	2
Major Curve Pre-op (Ntotal =27)	70.3°	68.3°	66.5°
Major Curve at Discharge (Ntotal =23)	22.2°	32.2°	55.0°
Major Curve at 6 months (Ntotal =18)	29.7°	45.2°	35.0°
Major Curve at 12 months (Ntotal =17)	33.8°	37.7°	40.0°
Major Curve at 24 months (Ntotal =19)	34.0°	33.8°	50.5°
Major Curve at 36 months (Ntotal =17)	40.4°	29.0°	50.5°
Major Curve at 48 months (Ntotal =11)	40.2	40.5	NA

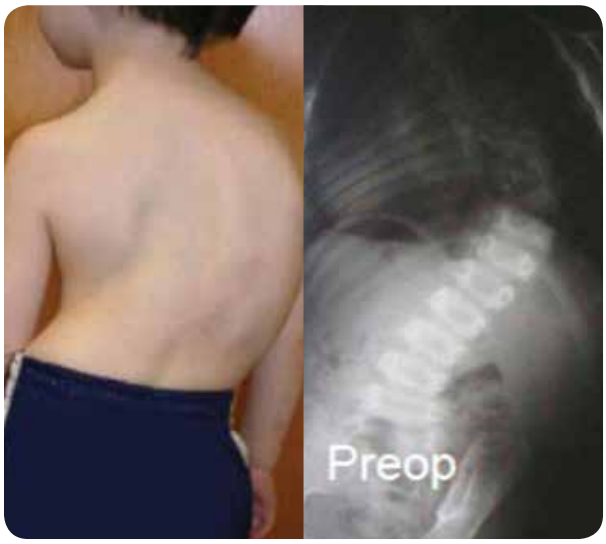
Radiographic Results *continued*

Using the mean preoperative number from the available patient data at the different time points, the percentage of curve correction and maintenance with the SHILLA™ System implant varied from 68% to 41% over time.

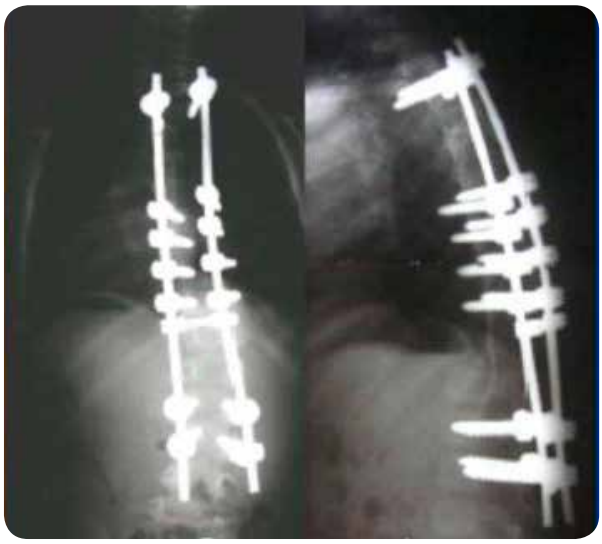


Case 1: SHILLA™ System Patient

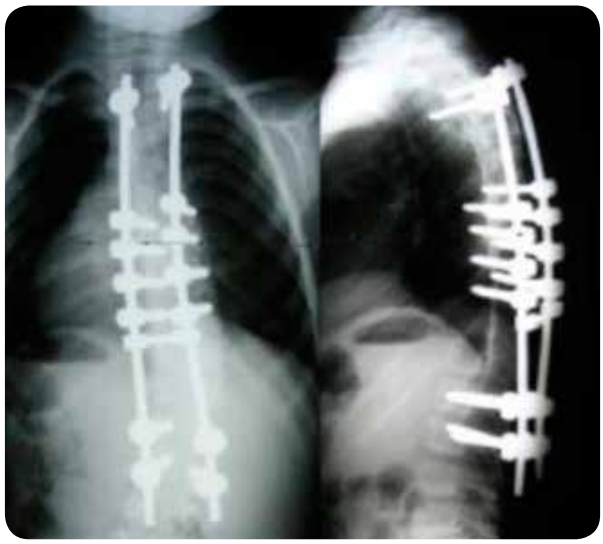
SHILLA™ System patient demonstrating correction maintenance and truncal height (T1-S1) increase over time. Images courtesy of Dr. R. McCarthy.



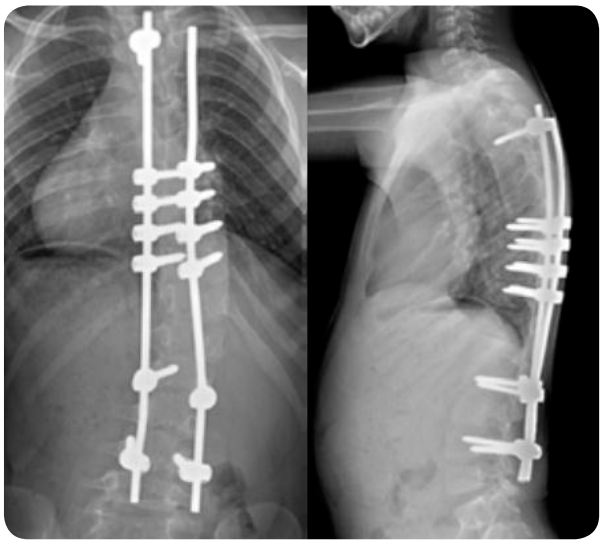
Pre-Op



3 Months Post-Op



2 Years Post-Op



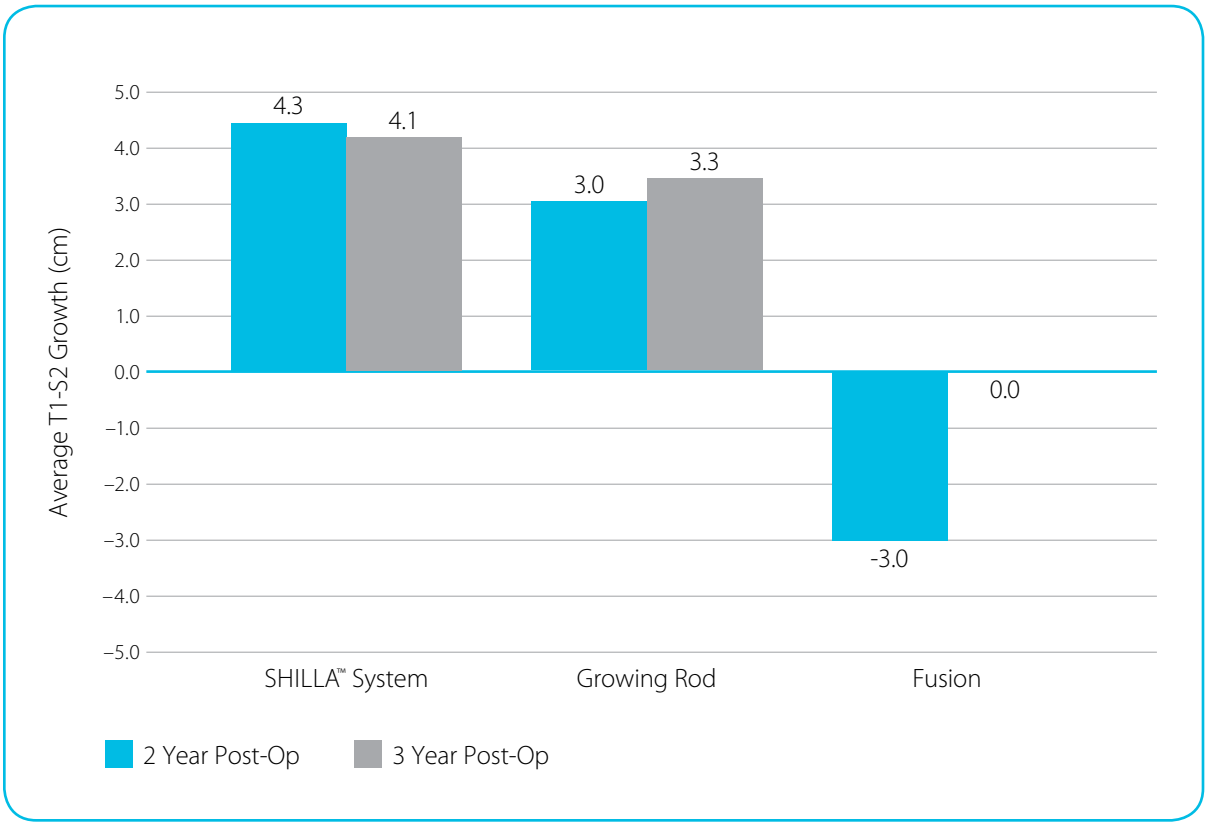
5 Years Post-Op

Patient Outcomes

SHILLA™ Growth Guidance System allowed natural growth (trunk height [T1-S1] increase) without the need for periodic distractions and rod lengthenings.

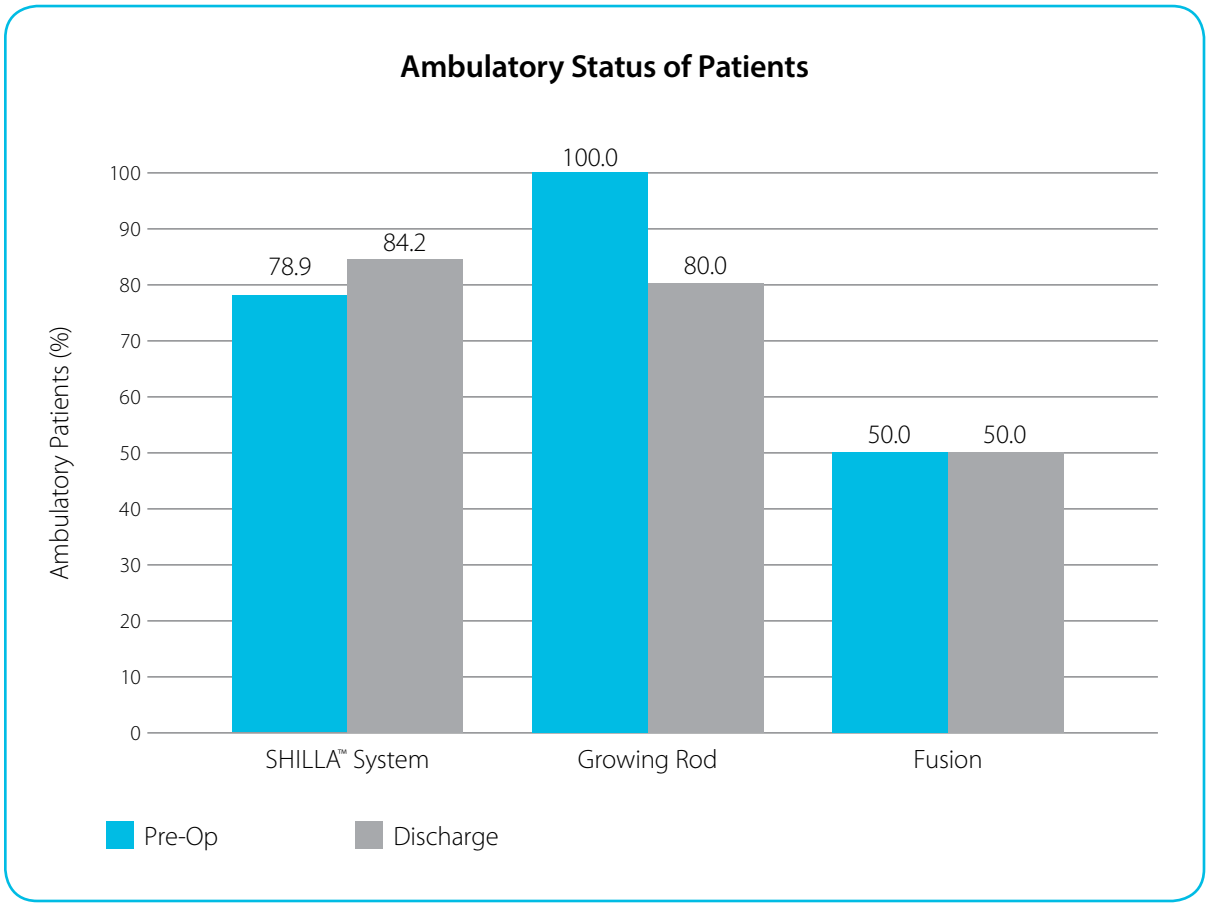
» At 2 years postoperatively, average T1-S2 growth in the SHILLA™ System group was 4.3cm compared to 3.0cm in the Growing Rod group.

» Three patients in both the SHILLA™ System group and the Growing Rod group outgrew their constructs and required additional surgeries.



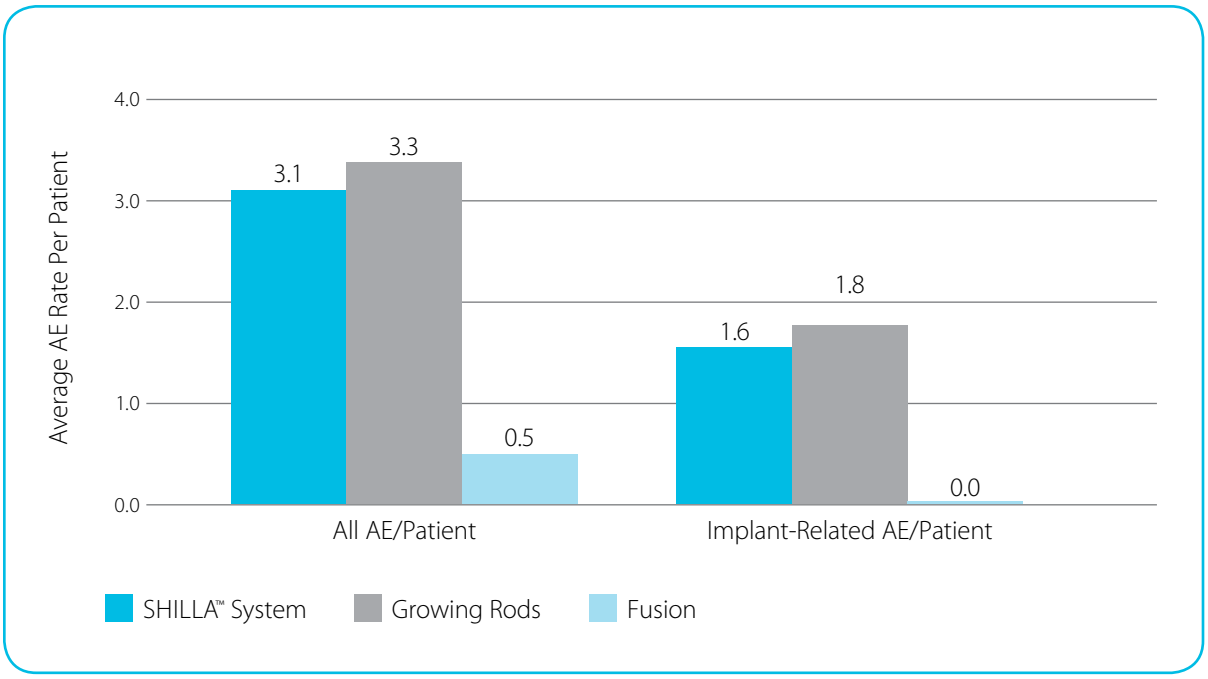
Patient Outcomes

- At discharge, 16 of the SHILLA™ System patients were ambulatory (vs. 15 ambulatory preoperatively).
- Status in the Fusion patients were unchanged.
- One Growing Rod patient was non-ambulatory at discharge and the status of another Growing Rod patient was unknown.
- No SHILLA™ System patients experienced any negative changes in ambulatory or motor function.



Adverse Events

- 84.2% of patients in SHILLA™ System group, 100% in the Growing Rod group, and 50% in the Fusion group had at least one adverse event (AE).
- There were 59 AEs in the SHILLA™ System group, 20 in the Growing Rod group, and 1 in the Fusion group.
- Average AE rate per patient was 3.1 for the SHILLA™ System compared to 3.3 in the Growing Rod group.
- Total number of AEs related to the implant (e.g., implant loosening, dislodgement, or breakage) was 31 in the SHILLA™ System group and 11 in the Growing Rod group (1.6 vs. 1.8 average AE rate per patient, respectively).



Summary of Types of Adverse Events

Type of Adverse Event Number of Events (Number of Affected Patients)	SHILLA™ System	Growing Rod	Fusion
Anatomical Technical Difficulty	5 (5)	0	0
Back and/or Leg Pain (of Back Etiology)	3 (3)	0	0
Cardiovascular (IEMI Stroke)	1 (1)	0	0
Endocrine	1 (1)	0	0
Gastrointestinal Other	3 (1)	0	0
Implant Displacement/Loosening/Breaking	20 (9)	10 (5)	0
Incision Related	1 (1)	2 (2)	0
Infection	6 (3)	1 (1)	0
Malpositioned Implant	1 (1)	0	0
Other	4 (2)	2 (1)	0
Respiratory	1 (1)	0	0
Skin Disorder	0	2 (2)	1 (1)
Spinal Event at Target Level	5 (5)	0	0
Trauma	2 (1)	1 (1)	0
Urogenital	1 (1)	0	0

Summary of Types of Adverse Events

Operative Measures

On average, the hospital stay for SHILLA™ System group was reduced 1.6 days compared to Growing Rod group and 11.4 days compared to Fusion group.

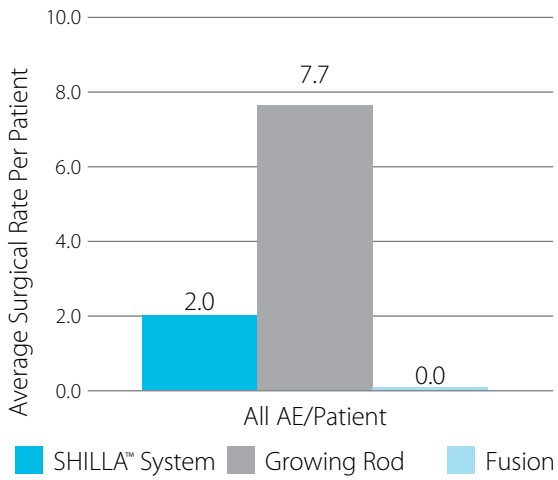
Surgical Outcomes	SHILLA™ System	Growing Rod	Fusion
N	19	6	2
Operative Time (hrs.)	5.2	4.4	4.3
Blood Loss (ml)	388.6	235	475
Hospital Stay (days)	5.1	6.7	16.5
Instrumented Level per Patient	12.95	14.5	16.0

Operating room time was greater in the SHILLA™ System group by approximately 50 minutes.

Repeat Operations/Second Surgeries

Types of secondary surgeries included procedures related to infection, and those related to the implant.

- There were 38 secondary surgeries for the SHILLA™ System group, 46 for the Growing Rod group, and 0 for the fusion group.
- Average secondary surgery rate was 2.0 per patient for the SHILLA™ System group and 7.67 per patient for the Growing Rod group.
- For second surgeries related to the index surgery, the rate



Summary of Secondary Surgical Procedures

Reason for Secondary Surgery (Number of Procedures/Number of Patients)	SHILLA™ System	Growing Rod
Spinal Surgery Related to Index Procedure	29 (12)	43 (6)
Non-spinal Surgical Procedures	8 (6)	3 (2)
Need for Additional Growth (Lengthening)	0	33 (5)
Broken or Bent Device	5 (3)	8 (5)
Dislodged, Loosened, or Migrated Implant	16 (7)	2 (2)
Prominent Implants	3 (2)	0
Malpositioned Device	3 (1)	0
Outgrown Device	3 (3)	3 (3)
Adjustment of Instrumentation	3(3)	0
Progression of Deformity	3 (2)	0
Infection or Wound Issue Related to Index Procedure	3(1)	3(2)
Other	8(5)	5(2)

was 1.5 per patient for the SHILLA™ System group and 7.17 per patient for the Growing Rod group.

Key Points

- Clinical data demonstrates SHILLA™ Growth Guidance System helped provide curve correction and maintenance while allowing for continued growth.
- SHILLA™ Growth Guidance System helped allow growth while reducing the average surgical rate per patient from 7.7, for Growing Rod, to 2.0 for SHILLA™.
- At 2 years postoperatively, average T1-S2 growth in the SHILLA™ System group was 4.3cm compared to 3.0cm in

the Growing Rod group.

» In the study, no SHILLA™ System patients experienced any negative changes in ambulatory or motor function.

References

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Important Product Information

IMPORTANT INFORMATION ON THE SHILLA™ GROWTH GUIDANCE SYSTEM

The SHILLA™ Growth Guidance System is intended for correction and maintenance of the correction of severe, progressive, multi-planar spinal deformities such as early-onset scoliosis. The device is designed to help attain spinal correction while allowing continued skeletal growth.

DESCRIPTION

The SHILLA™ Growth Guidance System consists of stainless steel components used to form a distinct spinal construct in growing children. The SHILLA™ Non-Locking Set Screw provides attachment of a spinal pedicle screw to a spinal rod. Unlike a typical set screw, which rigidly locks the vertical rod inside the connector housing to the pedicle screw, the SHILLA™ Non-Locking Set Screw captures the rod within the screw housing, but does not fix it rigidly to the pedicle screw.

The SHILLA™ Growth Guidance System consists of a construct that includes 4.5mm or 5.5mm diameter rods, fixed angle and multi-axial screws, and with CROSSLINK® plates. Additionally, the construct may be supplemented with sublaminar wire. All of the SHILLA™ Growth Guidance System implants are provided non-sterile. The SHILLA™ Growth Guidance System implants are not to be used with implants from other systems. **Never use stainless steel and titanium implant components in the same construct.**

As with all orthopedic and neurosurgical implants, SHILLA™ Growth Guidance System components should ever be reused under any circumstances.

INDICATIONS

The SHILLA™ Growth Guidance System is indicated for skeletally immature patients less than 10 years of age with the potential for additional spinal growth who require surgical treatment for correction and maintenance of the correction of severe, progressive, life-threatening early-onset spinal deformities, including early-onset scoliosis, which are associated with or at risk of thoracic insufficiency syndrome.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

- Active or significant risk of infection (immunocompromise)
- Suspected or documented metal allergy or intolerance
- Any patient having inadequate tissue coverage over the operative site

POTENTIAL ADVERSE EVENTS

The potential adverse events include, but are not limited to:

- Early or late loosening of the components including screw loosening or screw pull-out.
- Disassembly, bending, or breakage of the components.
- Foreign body (allergic) reaction to implants, debris, or corrosion products (from crevice, fretting, or general corrosion) including metallosis, staining, tumor formation, or autoimmune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, neurosis, or pain.
- Bursitis.
- Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, or reduction.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, or meningitis.
- Loss of neurological function (e.g., sensory or motor) including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, radiculopathy, pain, neuroma, or spasms.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, or muscle loss.
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone including the sacrum, pedicles, or vertebral body.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery including proximal junctional kyphotic deformity or distal junctional kyphotic deformity.
- Loss of or increase in spinal mobility or function.
- Inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stresses shielding.
- Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
- Hemorrhage, damage to blood vessels, thrombophlebitis, or occlusion.
- Hematoma, seroma, edema, wound necrosis, or wound dehiscence.
- Hypertension, embolism, stroke, or other types of cardiovascular system compromise.
- Reproductive system compromise including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems (e.g. pulmonary embolism, atelectasis, bronchitis, or pneumonia)
- Change in mental status
- Death

Note: Additional surgery may be necessary to correct some of these potential adverse events.

WARNING

A successful result is not always achieved in every surgical case. Preoperative symptoms and/or spinal deformity may be unrelieved or worsened. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. Further, the proper selection and compliance of the patient may greatly affect the results.

An implanted device should never be re-used unless otherwise specified. Implants which have come in contact with the patient are designed for single patient use only. Do not reuse, reprocess, or re-sterilize used implants. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of these implants and create a risk of contamination of the implants which could result in patient injury, illness, or death. Unused Implants that have not been in contact with the patient or the patient's blood may be re-sterilized and used in subsequent procedures.

PRECAUTIONS

The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this unique pedicle screw spinal system. The implantation technique is a technically demanding procedure that presents a risk of serious injury to the patient.

Preoperative and operating procedures including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants, are important considerations in the successful utilization of the system by the surgeon.

Important Product Information *continued*

ADDITIONAL PREOPERATIVE PRECAUTIONS
It may be appropriate to consider the need for additional procedures prior to implantation of the SHILLA™ Growth Guidance System including preoperative halo traction or anterior spinal surgery.

Additional adjunctive surgical procedures may be required in conjunction with implantation of the SHILLA™ Growth Guidance System including but not limited to posterior spinal column osteotomy procedures (Ponte type, Smith Petersen type), pedicle based osteotomy procedures, vertebral body decancellation procedures, vertebral column resection procedures, thoracoplasty procedures, anterior spinal surgery, and iliac bone graft harvest procedures.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

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