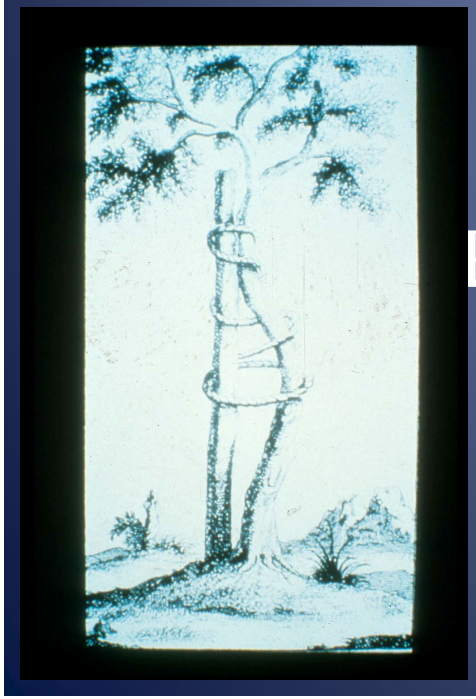
A Comparison of SHILLA GROWTH GUIDANCE SYSTEM™ (SGGS) and Growing Rods in the Treatment of Spinal Deformity in Children Less than 10 Years of Age



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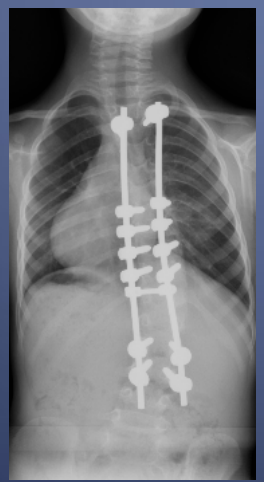
Disclosures

- Scott Luhmann
  - Consultant: Medtronic, Orthofix
  - Education: Medtronic, Stryker Spine
  - Royalties: Lippincott, Globus
- Richard McCarthy
  - Consultant: Medtronic

Introduction

- Shilla construct was first reported at IMAST in 2007.
- Subsequent reports have documented:
  - Good correction of the coronal Cobb: 51.8 % at 2 yr f/u
  - Fewer surgeries (75% less) than would be expected for growing rod treatments
- Direct comparison between matched patient cohorts of Shilla™ and GR has not been previously reported.
- The purpose of this study is to report the radiographic and clinical outcomes of Shilla and GRs in the treatment of scoliosis in children <10 years of age.



Little Rock, Arkansas

Methods

St. Louis, Missouri

- Two-center retrospective study of Shilla™ as an alternative to growing rods (GR) to support HDE submission for FDA approval.
- Inclusion criteria:
  - Progressive scoliosis >40 degrees
  - Thoracic or lumbar spine main curves
  - Less than 10 years of age at index procedure
  - Treated w/ GR or Shilla™, minimum 6 vertebral levels
- Radiographic and clinical data were obtained preoperatively through final f/u.

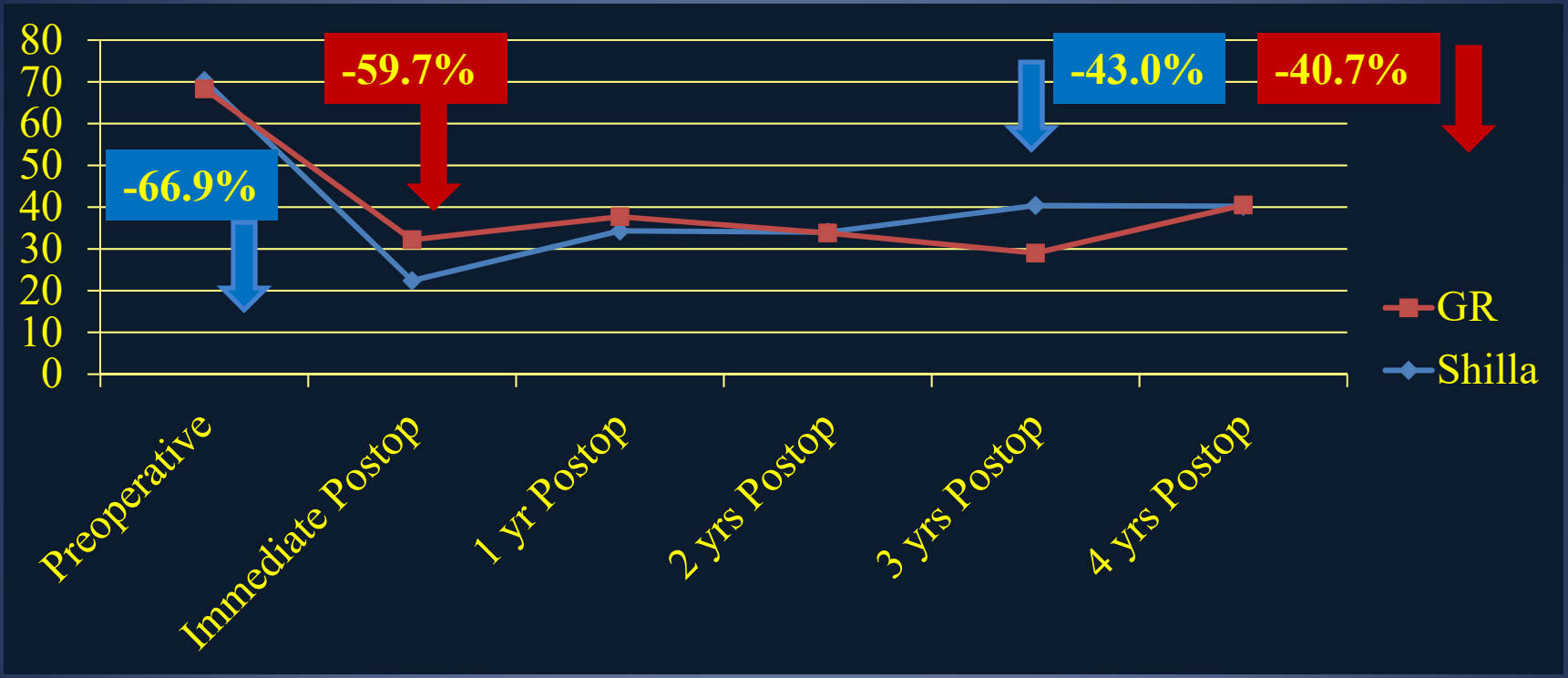
Methods

	# patients	Mean age	Mean f/u	Ambu-latory?	Curve Location
Shilla™	19 12 f:7 m	6.1 y	3.8 y	15/19 (79%)	PT 1 MT 14 TL/L 4
GR	6 4 f:2 m	5.8 y	3.6 y	6/6 (100%)	MT 6

Results

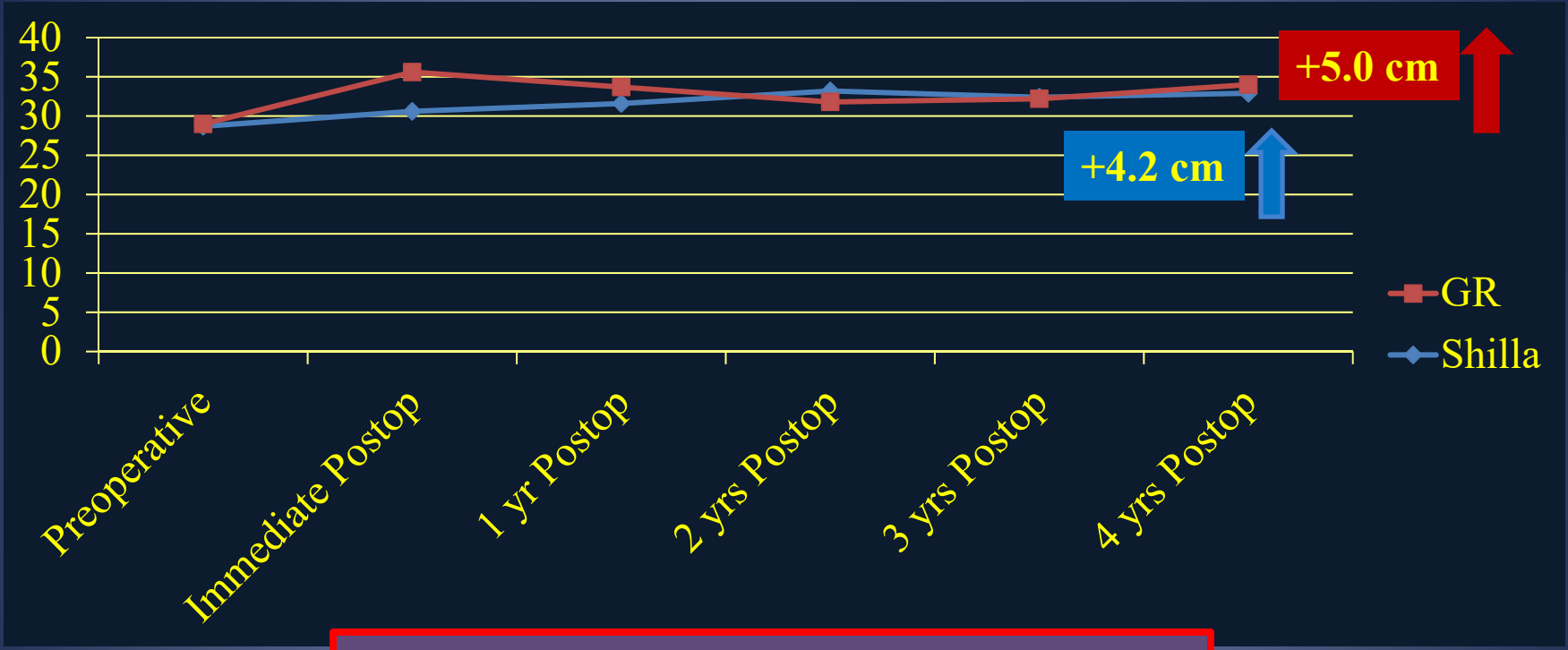
	Mean OR time	Mean EBL	Mean hospital stay	Diagnoses
Shilla™	5.2 h	389 cc	5.1 d	IS: 7 Syndromic: 7 NM: 5
GR	4.4 h	235 cc	6.7 d	IS: 4 Syndromic: 1 NM: 1

Main Curve: Cobb Measure



	Preop	Immediate Postop	1 yr Postop	2 yrs Postop	3 yrs Postop	4 yrs Postop
Shilla™	70.3°	22.4°	34.3°	34.0°	40.4°	40.2°
GR	68.3°	32.2°	37.7°	33.8°	29.0°	40.5°

T1-S1 length (mean, cm)



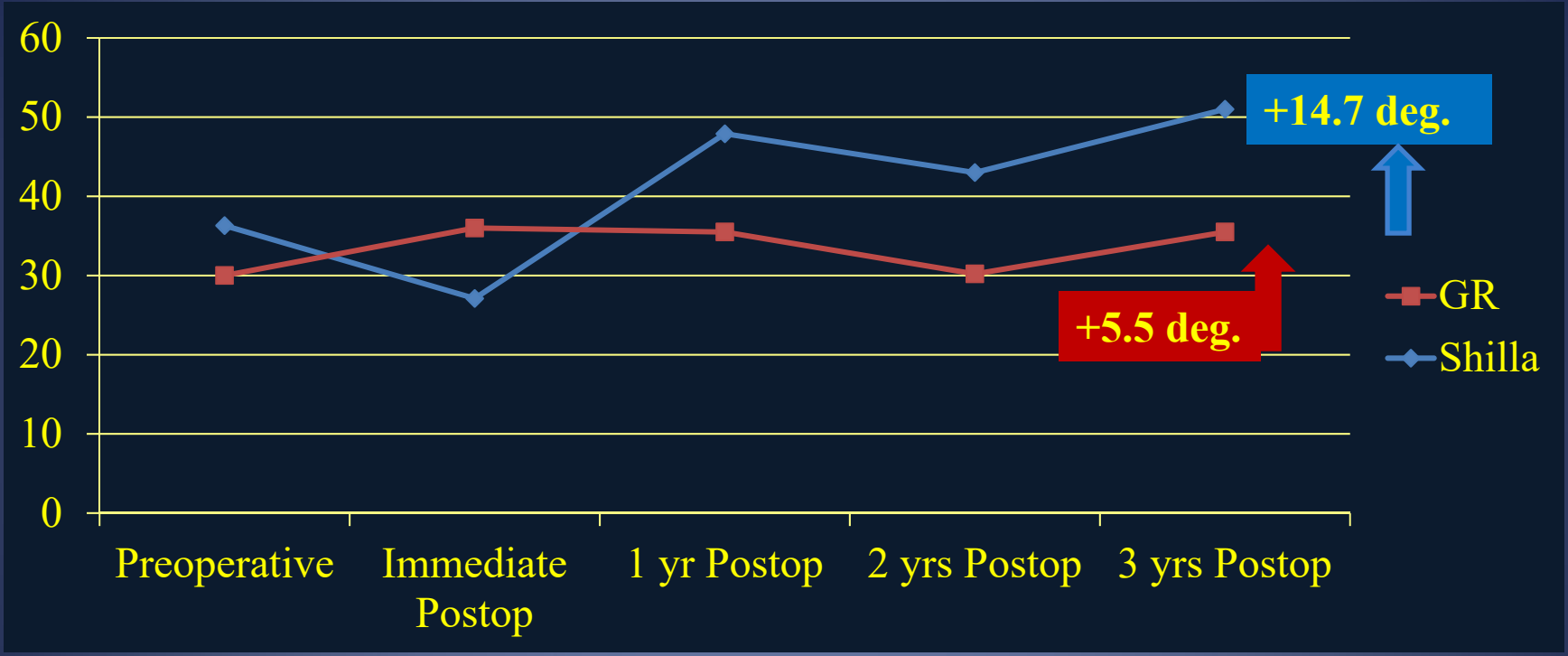
	Pre	3 yrs Postop	4 yrs Postop
Shilla™	28.	32.4	32.9
GR	29.	32.2	34.0

Mean growth T1-S1/month

Shilla™ : 0.14

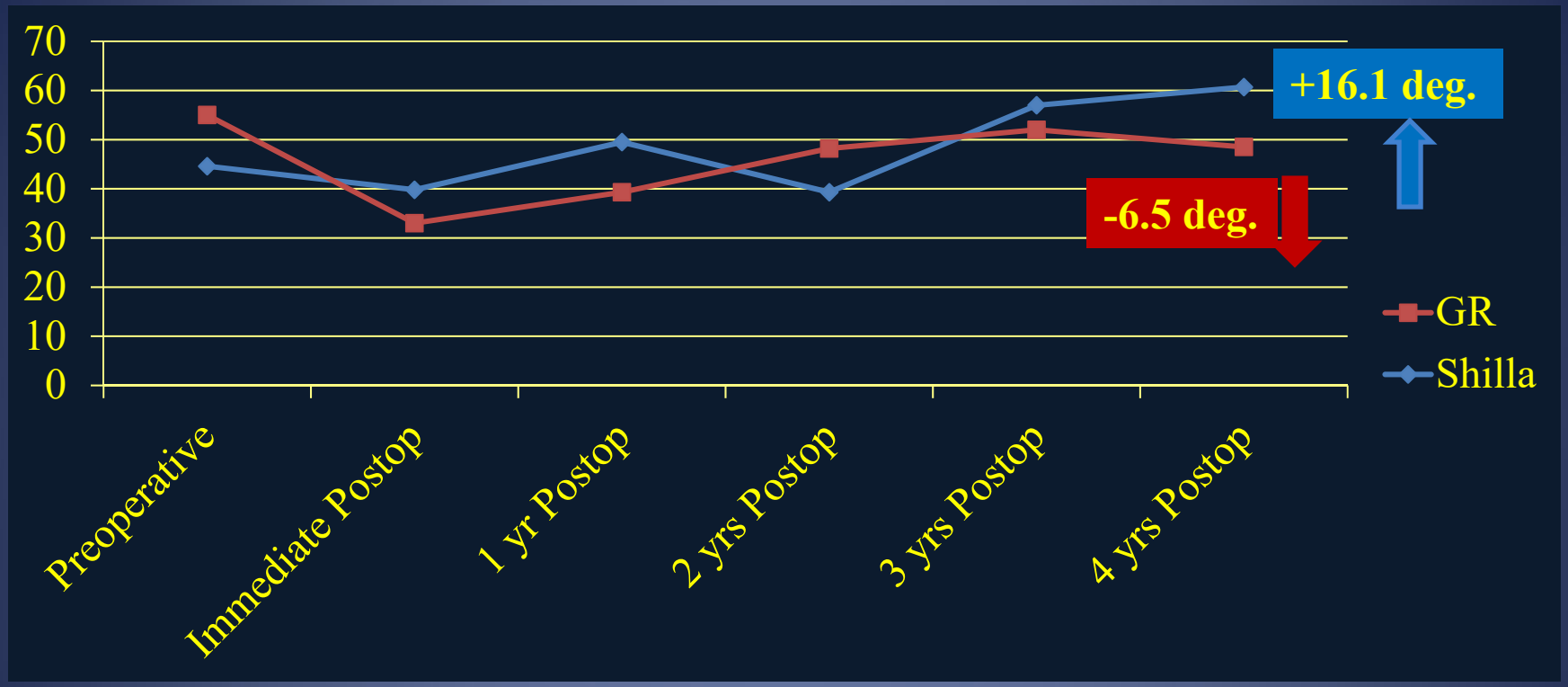
Growing Rods: 0.11

T2-T12 Kyphosis (mean)



	Preop	Immediate Postop	1 yr Postop	2 yrs Postop	3 yrs Postop
Shilla™	36.3°	27.1°	47.9°	43.0°	51.0°
GR	30.0°	36.0°	37.5°	30.2°	35.5°

T12-S1 Lordosis (mean)



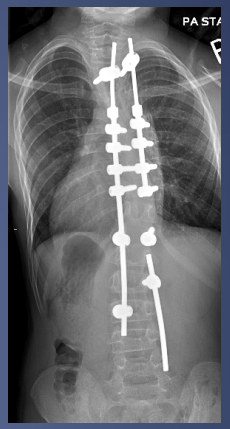
	Preop	Immediate Postop	1 yr Postop	2 yrs Postop	3 yrs Postop	4 yrs Postop
Shilla™	-44.6°	-39.8°	-49.5°	-39.3°	-57.0°	-60.7°
GR	-55.0°	-33.0°	-39.3°	-48.2°	-52.0°	-48.5°

Reoperations

- Shilla™ :
  - 7 of the 19 patients had no reoperations (37%)
  - 12 of the 19 patients (63%) had a total of 29 reoperations
  - Reoperation rate: 1.5 reoperations/patient
- Growing Rods:
  - All 6 Growing rod patients (100%) had reoperations
  - Total of 43 reoperations (33 were routine lengthenings)
  - Reoperation rate:
    - Mean 5.5 reoperations for lengthenings
    - Mean 1.7 reoperations/patient for non-lengthening surgeries
    - Overall 7.2 reoperations/patient

Complications/Adverse Events

- None intraoperatively in either group
- Implant-associated AE:
  - Shilla™ : 30 in 13 patients (68.9%)
  - GR: 11 in 5 patients (83.2%)
- Surgical Site Infection:
  - Shilla™ : 1 (5.3%)
  - GR: 0 (0%)



Conclusion

- The SHILLA™ GROWTH GUIDANCE SYSTEM compares favorably with traditional growing rod constructs in terms of correction of the major curve, spinal length and growth, and maintenance of sagittal alignment.
- Similar frequency of non-lengthening surgeries between the groups (1.5 for Shilla, 1.7 for GR)
- Overall reoperation rate is 1.5 for Shilla and 7.2 for GR
- The greater than four-fold decrease in secondary surgeries makes the Shilla growing rod an attractive alternative to minimize comorbidities associated with additional surgeries.