Next Generation of Growth-Sparing Techniques: Preliminary Clinical Results of a Magnetically Controlled Growing Rod (MCGR) in 14 Patients

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Disclosures

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Introduction

Growth modulation with current Growing Rod (GR) technique requires frequent surgical lengthenings and is associated with a high risk of complications

Complications of Growing-Rod Treatment for Early-Onset Scoliosis

Analysis of One Hundred and Forty Patients

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Investigation performed at San Diego Center for Spinal Disorders, La Jolla, California

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- The complication risk increased by 24% for each additional surgical procedure.
- Goal of remotely controlled devices: To reduce frequency of surgeries

Introduction

- The use of remotely controlled lengthening devices has been previously reported. (Takaso et al., Soubeiran et al.)
- Previous study of MCGR in an in-vivo porcine model showed its safety and efficacy, *achieving 80% of the targeted distraction. (Accepted Spine 2011)*
- The goal of this study is to evaluate the safety and efficacy of the MCGR procedure in patients with early onset scoliosis

MCGR Device Description

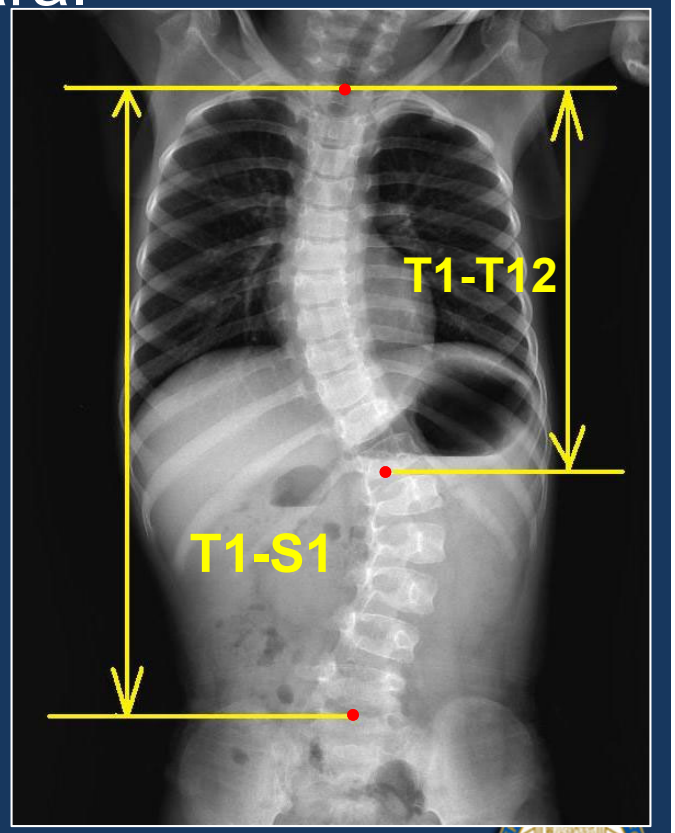
- Implantable Ti rod with a telescopic actuator portion that has a small internal magnet

- **CE marked in Europe (Oct 09), not yet FDA approved in USA**

- Rotation of external magnets can rotate the internal one and shorten or lengthen the attached rod

Materials and Methods

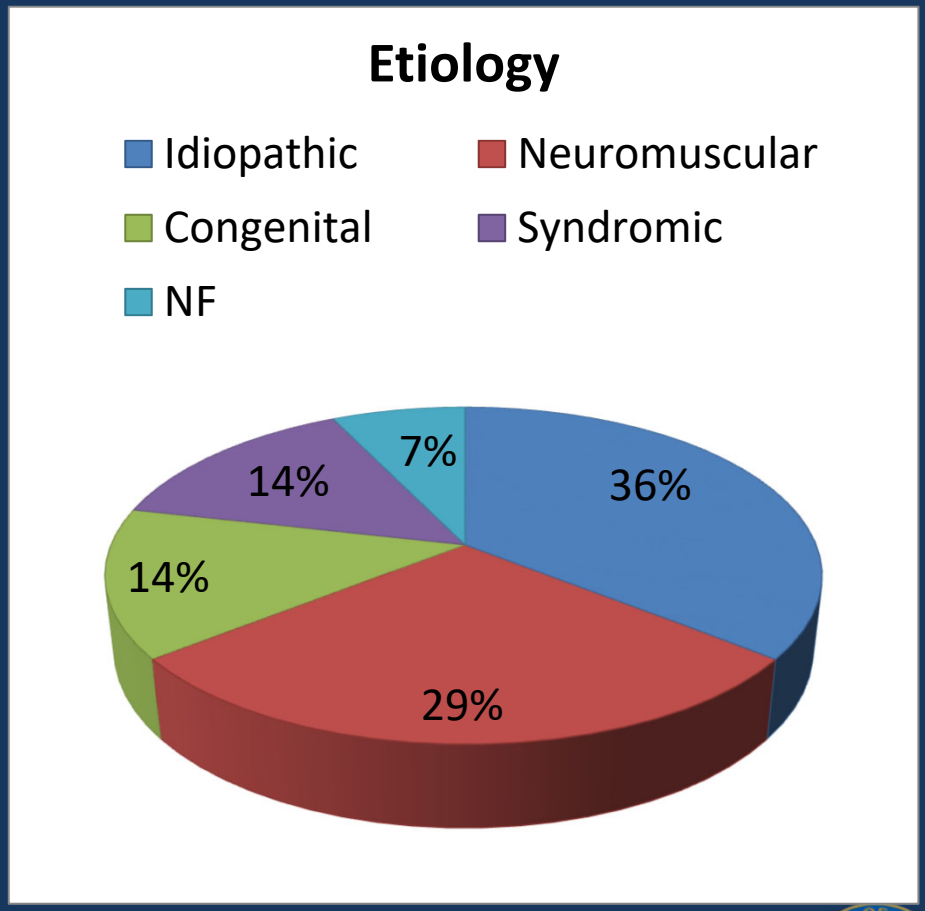
- From Nov-09 to Dec-10, a total of 33 patients underwent the **MCGR** procedure in 4 centers in Hong Kong, London, Cairo and Ankara.
- 14 patients met the inclusion criteria
  - (1) EOS of any etiology
  - (2) MCGR procedure
  - (3) Minimum of 3 distractions
- T1-T12 and T1-S1 heights were recorded before and after each distraction



Materials and Methods

- 14 patients: 7 M and 7 F
- Mean age: 8 y+10 m
  (3 y+6 m to 12y+7 m)

- 14 initial surgeries
- 91 distractions
- There were 10 thoracic, one thoracolumbar and 3 lumbar curves.



Results

- An average of 6.5 distractions per patient
- 5 single rod (SR) and 9 dual rod (DR)
- Average of 10 months follow up
- Mean time between index surgery and the start of first distraction was 66 days
- The mean interval between two subsequent distractions was 43 days

Results (Cobb)

	Mean Pre-op	Mean Post-op	Correction	Final	Correction (%)
Overall group	57°	35°	38%	35°	38%
Single Rod (N=5)	59°	38°	36%	38°	36%
Dual Rod (N=9)	55°	31°	**44%**	34°	38%

There was better initial Cobb correction with dual rod

Results

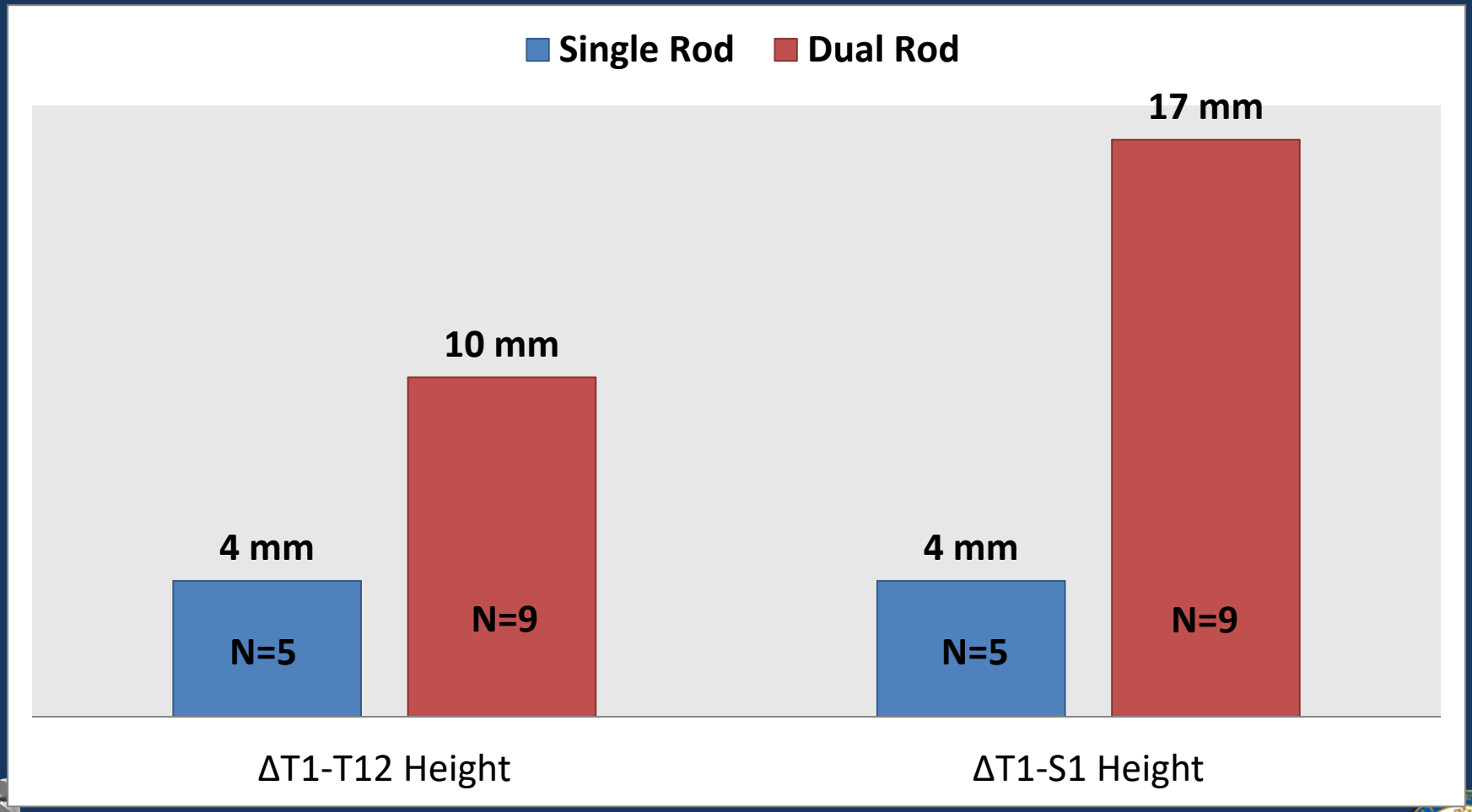
Two cases had previous surgery:

- One previous short anterior lumbar fusion after hemivertebra excision
- One previous traditional GR

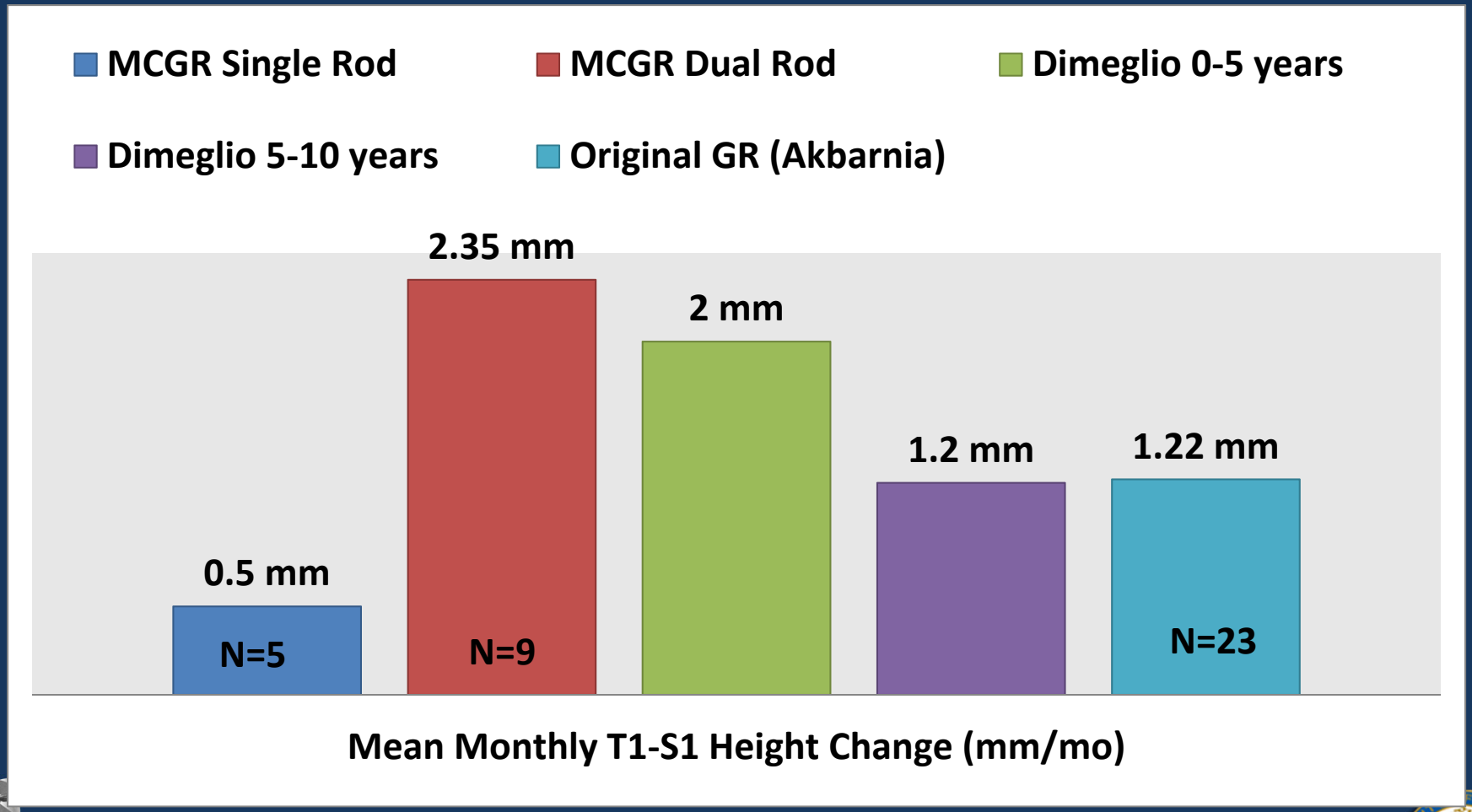
The most cephalad and caudad instrumented levels in 14 patients are shown in the following table.

Level	T1	T2	T3	T4	T5	T6
Number	-	5	8	-	1	-
Level	L1	L2	L3	L4	L5	Pelvis
Number	3	1	8	1	-	1

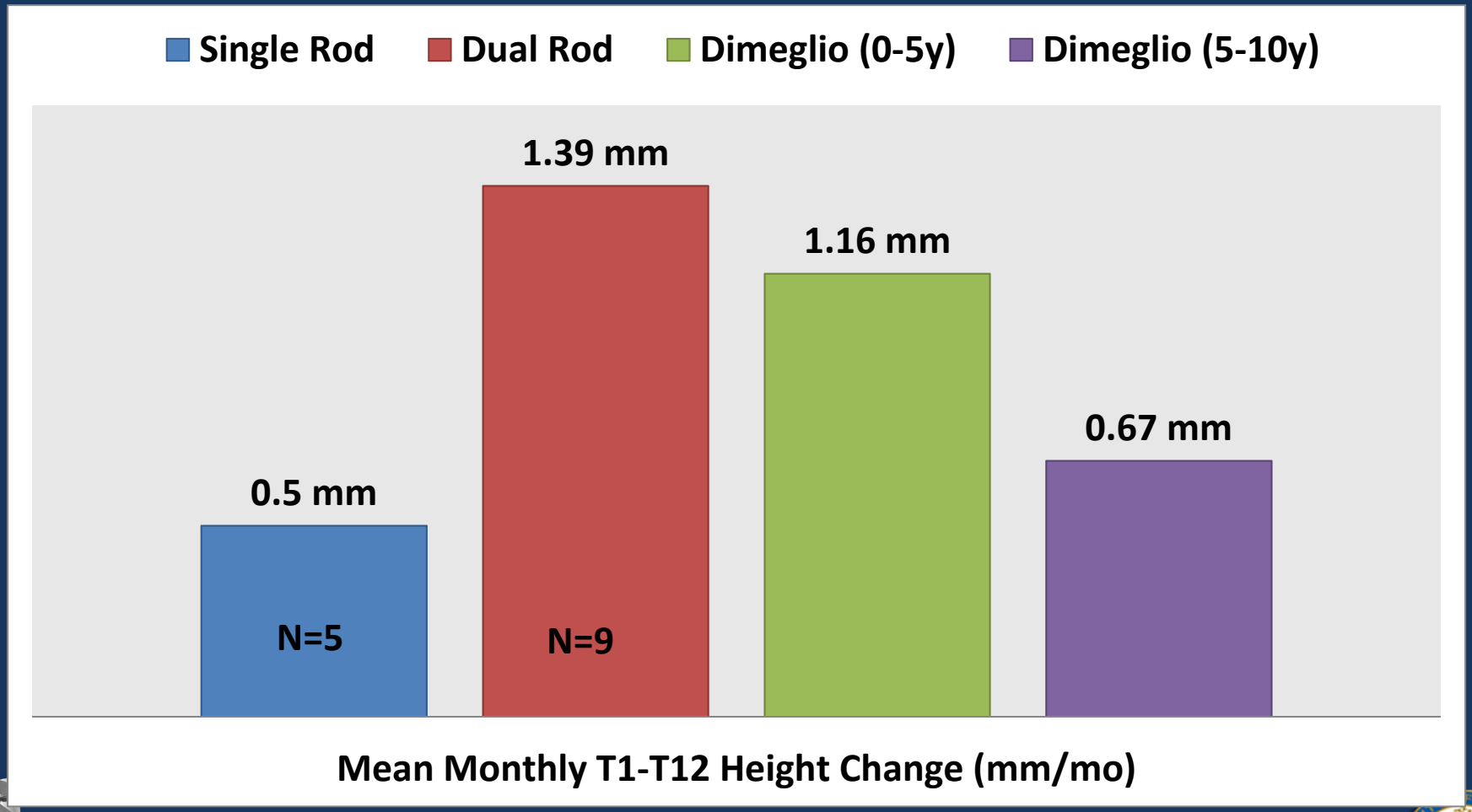
Results - ΔT1-T12 and ΔT1-S1 Height



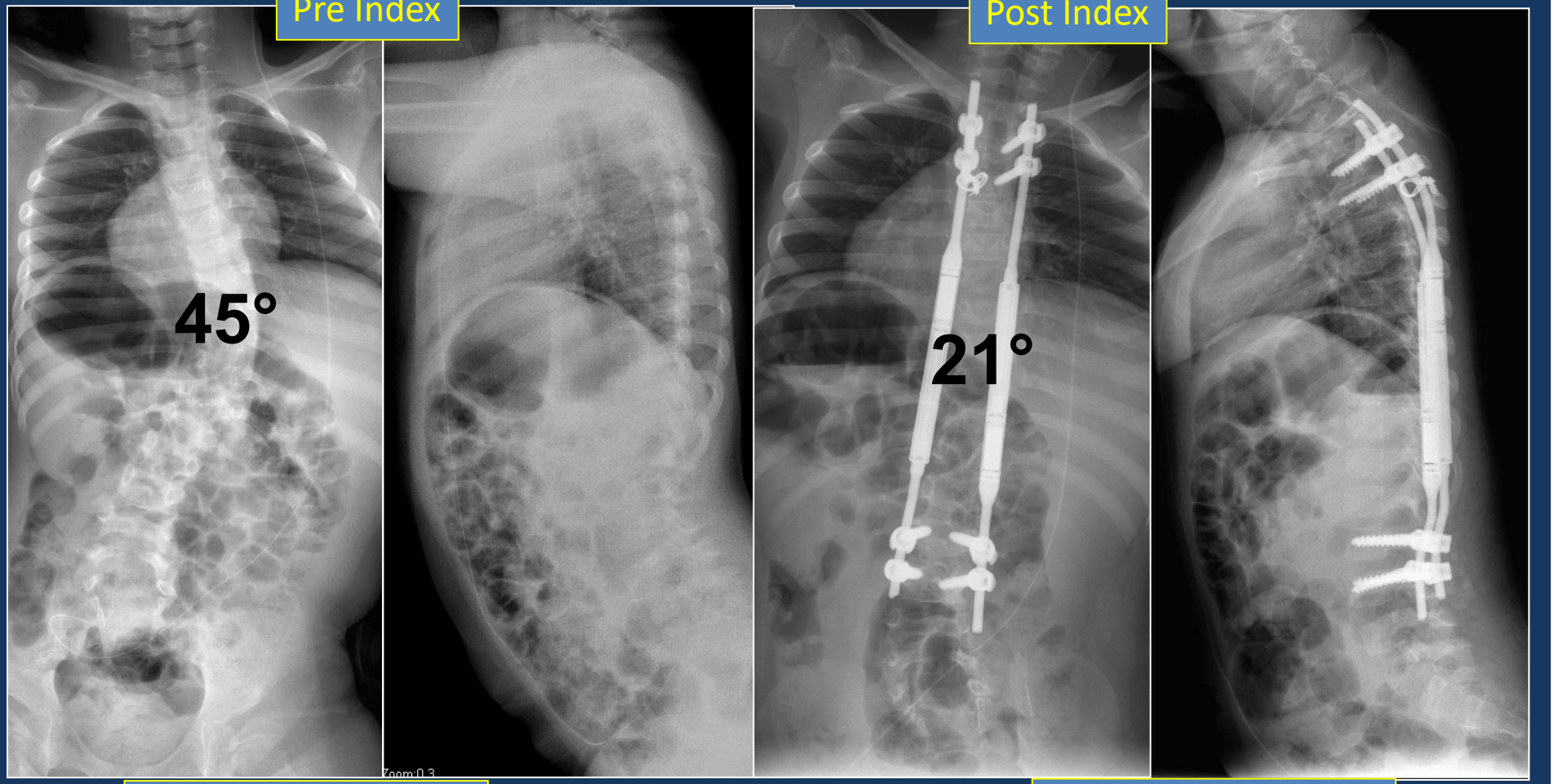
Results - Mean Monthly T1-S1 Height Change



Results - Mean Monthly T1-T12 Height Change



Case one: 5.5 y/o Female (NM)



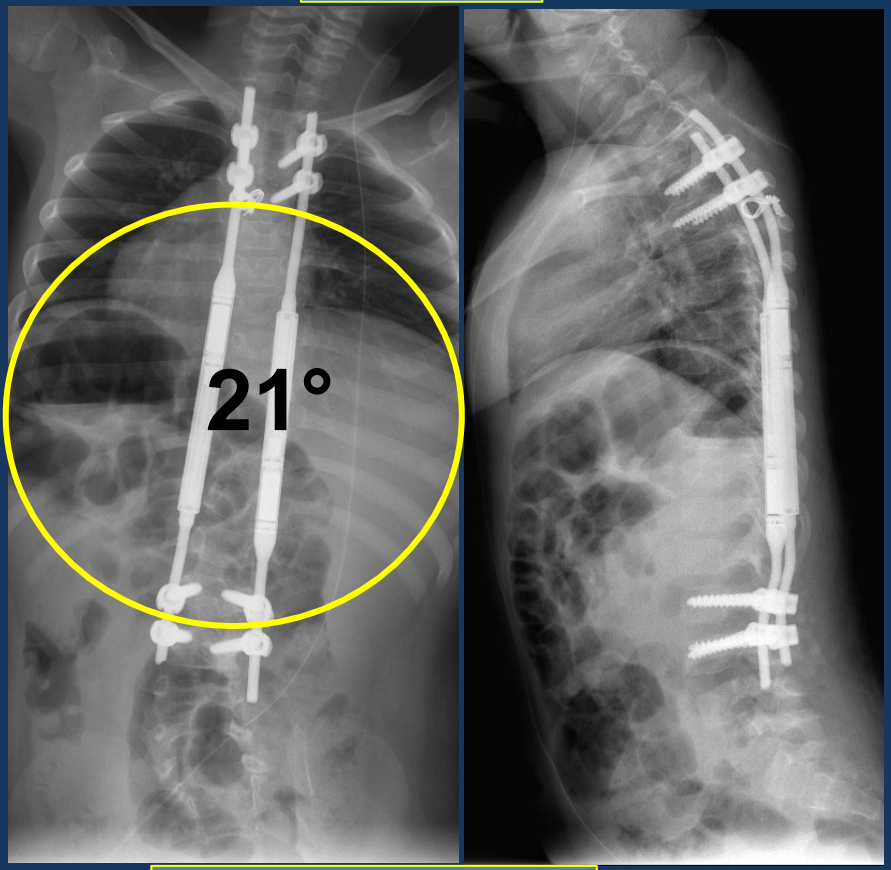
T1-T12: 176 mm
T1-S1: 251 mm

ΔT1-T12: 5 mm
ΔT1-S1:10 mm

T1-T12: 181 mm
T1-S1: 261 mm

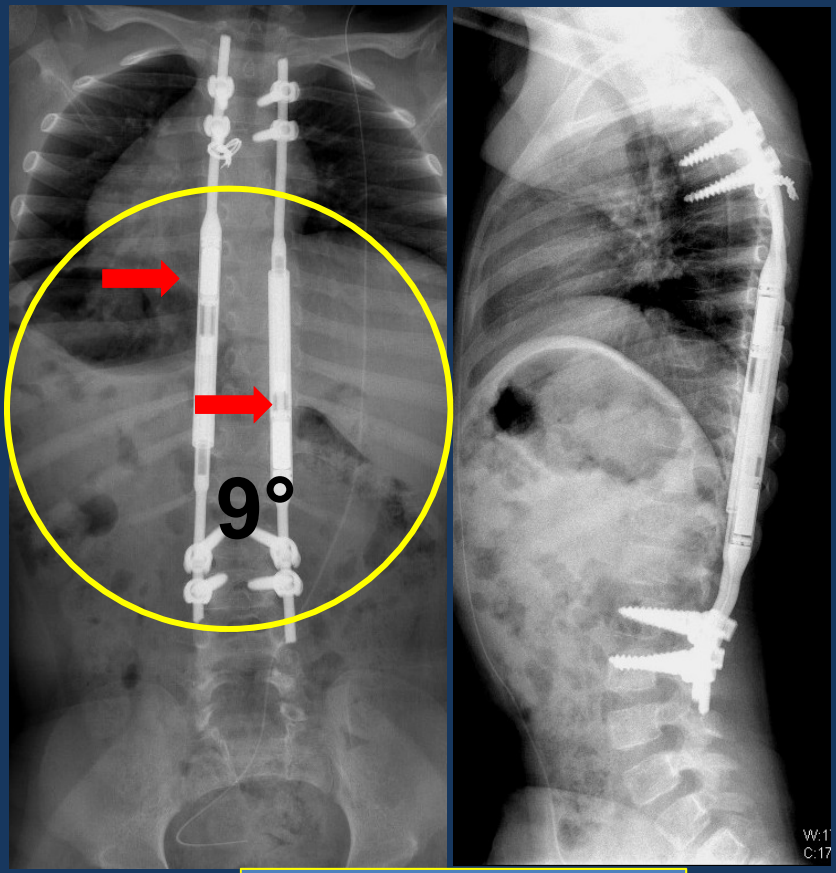
Case one: A 5.5 y/o NM female

Post Index



T1-T12: 181 mm
T1-S1: 261 mm

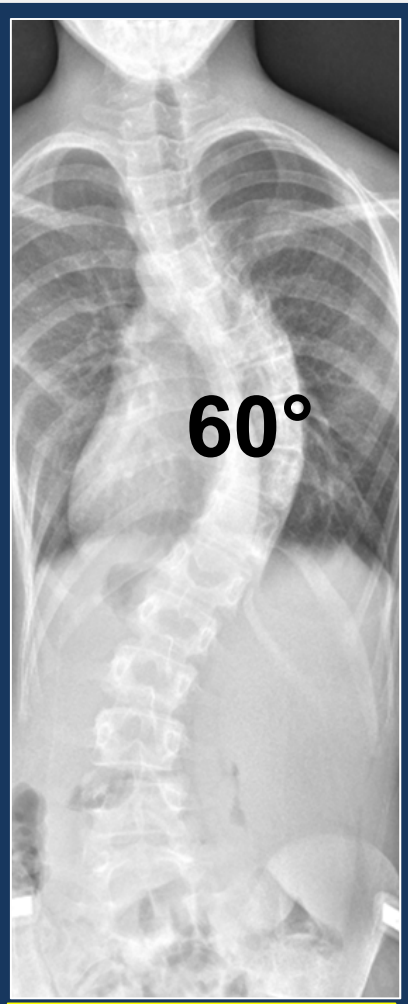
Latest Follow up

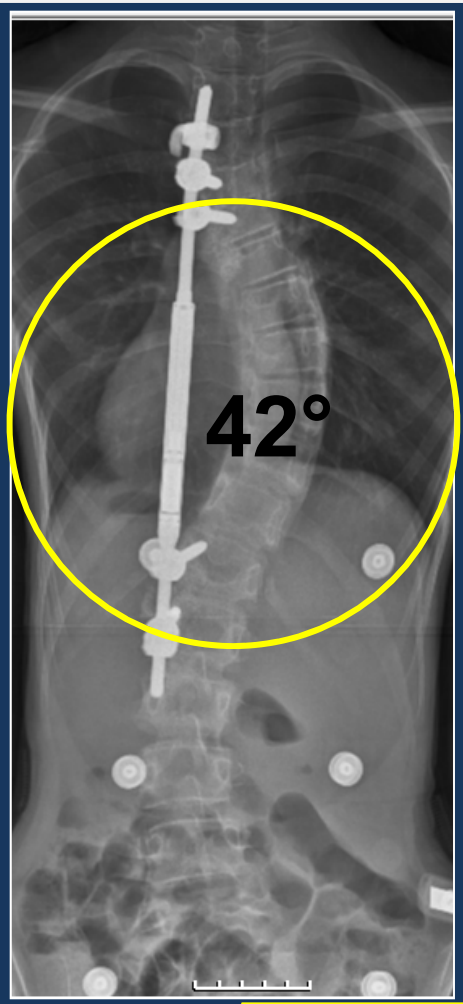


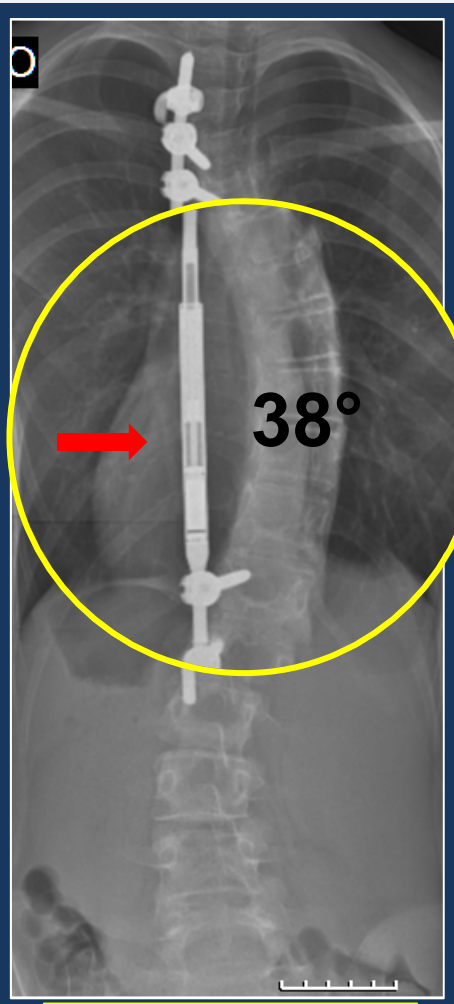
T1-T12: 193 mm
T1-S1: 292 mm

ΔT1-T12: 11 mm
ΔT1-S1: 31 mm

Case 2- Idiopathic, 4 distractions over 6 months







T1-T12: 204.5 mm
T1-S1: 330.3 mm

ΔT1-T12: 24 mm
ΔT1-S1: 39.1 mm

T1-T12: 228.5 mm
T1-S1: 369.4 mm

ΔT1-T12: 8.2 mm
ΔT1-S1: 8.2 mm

T1-T12: 236.7 mm
T1-S1: 377.6 mm

Complications

- Superficial infection in one patient (SR) (medical and local treatment)
- Prominent implant in one patient (DR)

- Partial loss of height after index surgery (3 SR) and after distractions (14 of the 91, 1 DR+13 SR) was observed

Conclusion

- MCGR is safe and effective surgical treatment in progressive EOS
- Since It eliminates repeated surgery, it may be an alternative to the traditional GR technique
- Increase of height of the T1-T12 and T1-S1 is comparable to normal children and those who are treated with the standard GR

Conclusion

- There was no major implant-related complication
- Dual rod patients showed better initial correction of coronal deformity and better monthly height increase of T1-T12 and T1-S1
- Additional follow-up and a larger cohort study is underway to confirm these initial findings

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THANK YOU!