

Diminishing Returns of Magnetically Controlled Growing Rod Lengthenings Over Time

ICEOS

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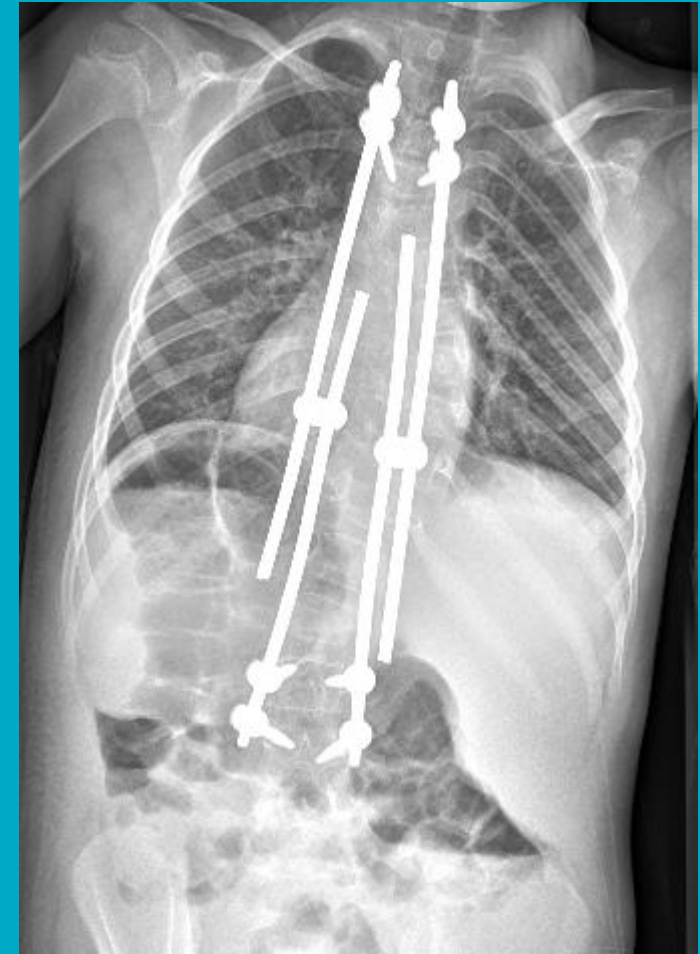
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Early Onset Scoliosis

- Onset of scoliosis prior to age 10
- Treatment is focused on controlling the curve while preserving growth of the spine and chest wall
 - Observation
 - Casting
 - Bracing
 - Surgery

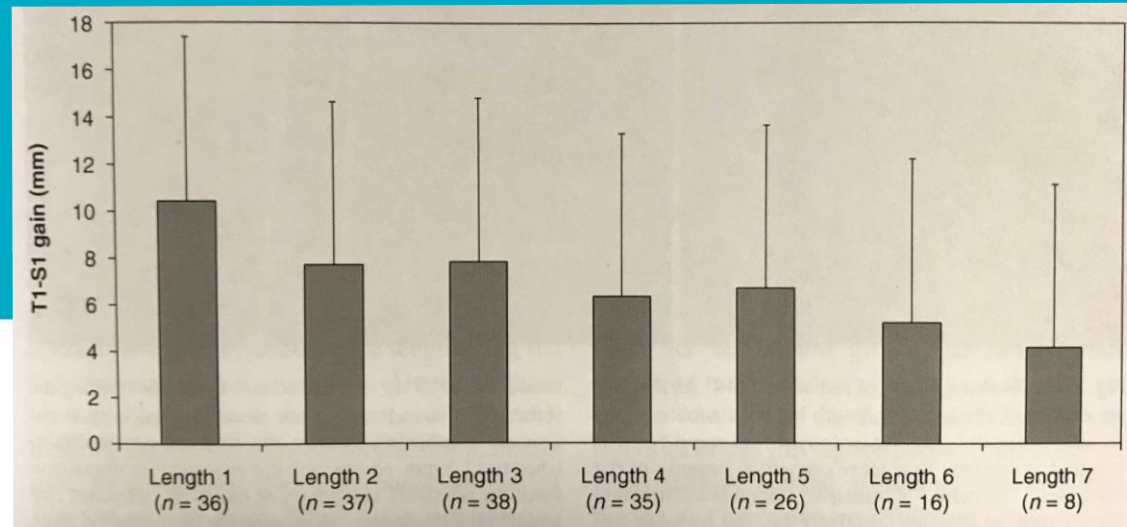
Traditional Growing Rods

- Fixation at the top and bottom of construct
- Repeat lengthening approximately every 6 months
- Repeated exposure to anesthesia
- 58% of patients will have at least one complication (Williams et al)
 - Wound complications
 - Implant complications



TGRs and Diminishing Returns

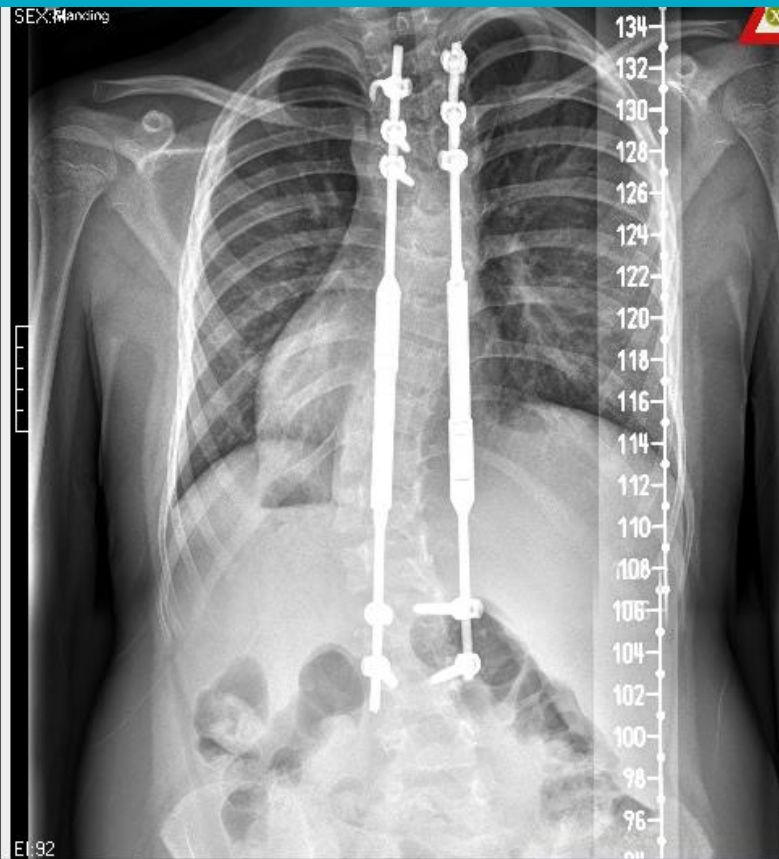
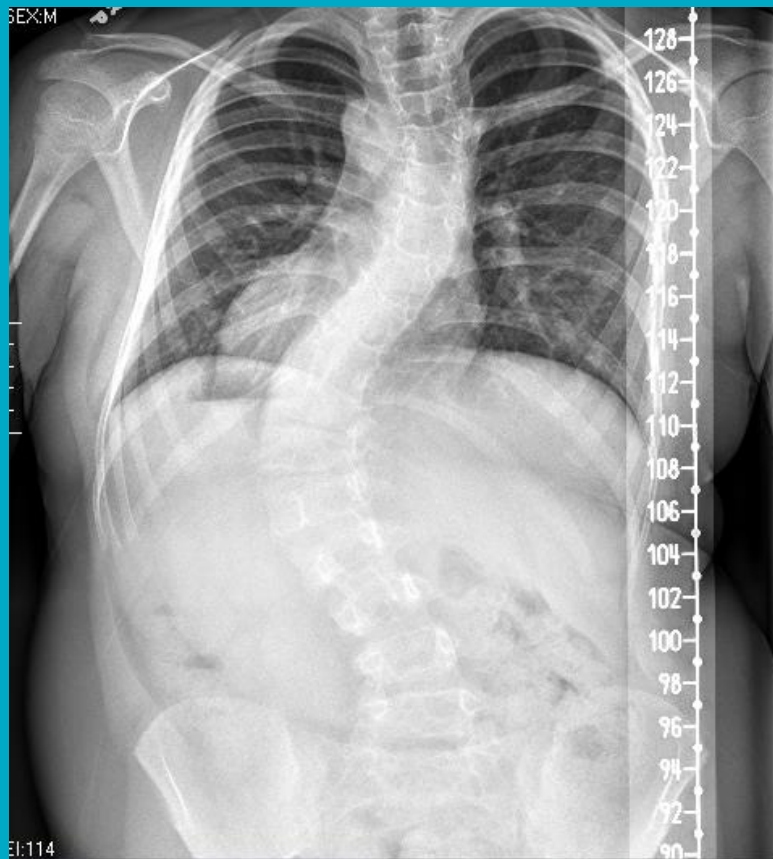
- Less distraction achieved, measured by T1-S1 length gain, at each repeated lengthening (Sankar et al)
- Due to:
 - Progressive stiffness of the immature spine or
 - Autofusion of the spinal segments



Sankar et al, Spine 2011

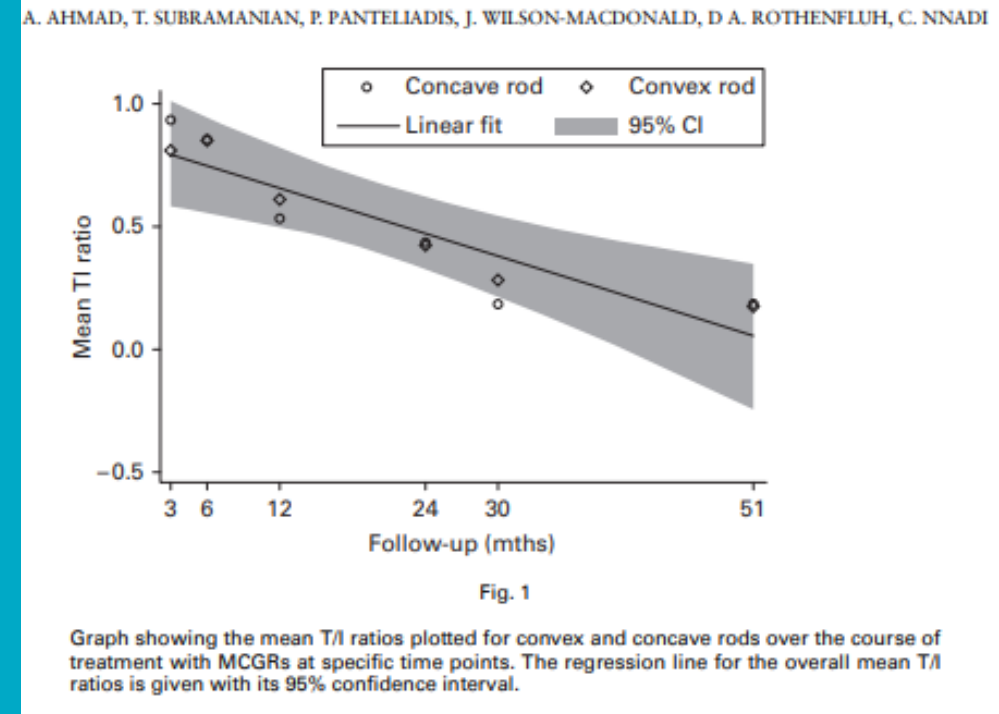
Magnetically Controlled Growing Rods

- Approved for treatment of EOS in the US by the FDA in 2014
- Fixation at top and bottom connected by a MCGR
- Distractions every 1-4 months with an external remote control (ERC) device
- Goals:
 - Minimize return trips to OR and repeated exposure to anesthesia
 - More closely resemble actual patient growth



Distraction of MCGRs

- Studies have shown that the actual distraction achieved is less than expected according to the amount on the ERC
 - Gilday et al – 86% (ultrasound)
 - La Rosa et al – 68% (radiographs)
 - Rolton et al – 36% (radiographs)
- A study by Ahmad et al showed a decrease in the intended to observed distraction ratio of MCGRs over time



Ahmad et al, Bone Joint
Journal 2017

Purpose

1. Assess the intended versus actual lengthening of MCGRs for sequential lengthening sessions in EOS patients with a minimum of 2 years follow-up.
2. Assess radiographic outcomes and complications requiring unplanned return trips to the OR.

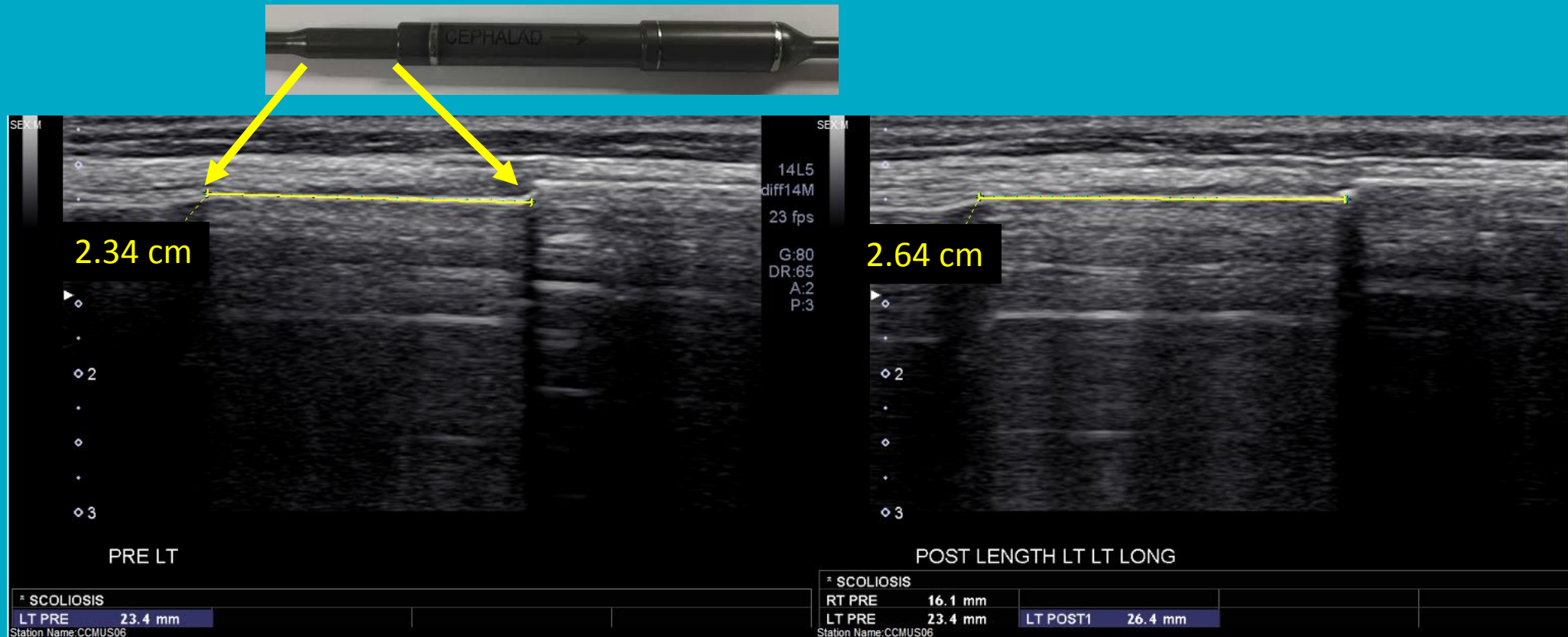
Methods

- Retrospective review of a single institution's MCGR patients from 2014-2017 with a diagnosis of EOS and a minimum of 2 years follow-up
- Demographic data, clinical data regarding each lengthening session, and radiographic measurements were analyzed
- Statistical methods
 - Student t-test for means
 - Pearson correlation analysis

Lengthening Protocol

- Lengthening sessions were planned at 3 month intervals
- Up to 2 lengthening attempts were made per rod per patient
- Most distractions were programmed for 3 mm of distraction and increased to 5 mm at age 10 for idiopathic and idiopathic-like curves.
- Distraction amount was measured on ultrasound (Stokes et al) for 295 of the sessions with the remaining 7 sessions determined on radiographs

Ultrasound to determine rod length



Before

After

Percent Distraction Achieved

- Percent distraction achieved was calculated as follows:
 - % Distraction Achieved = $\frac{\text{Change in rod length}}{\text{Programmed ERC amount}}$
- For those who had two attempts in a session:
 - % Distraction Achieved = $\frac{\text{Change in rod length attempt \#1 + attempt \#2}}{\text{Programmed ERC amount for attempt \#1 + attempt \#2}}$

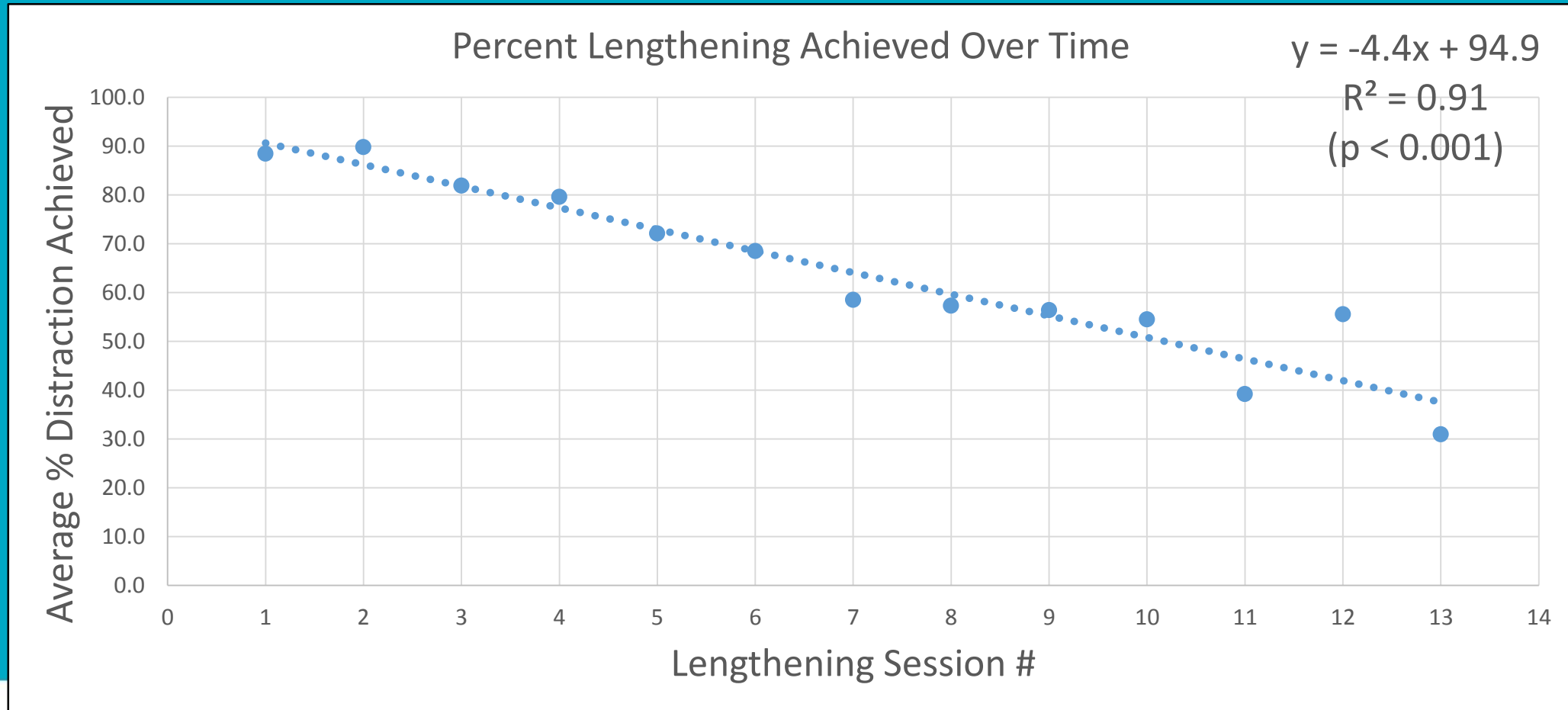
Patients

- 34 patients - 19 males and 15 females
- Diagnoses included: 8 idiopathic, 1 congenital, 13 neuromuscular, and 14 syndromic scoliosis
- 20 primary and 14 conversion procedures
- All patients initially had dual rod constructs
- Fixation: 33 patients with hooks and/or pedicle screws plus sublaminar bands, if necessary; 1 patient had rib fixation proximally and s-hooks distally.

Patients

- Mean age at MCGR insertion was 7.8 ± 2.77 years (range 4.1-12.2)
- Mean follow-up was 31.8 ± 5.54 months (range 24 - 42 months)
- A total of 302 lengthening sessions were included
- Average of 8.88 ± 1.96 (range 3-13) lengthening sessions per patient
- Average time between each lengthening session was 105.78 days

Results – Diminishing Returns



Results - Details of Lengthening Sessions

Lengthening Session	1	2	3	4	5	6	7	8	9	10	11	12	13
# of Patients	34	34	34	33	33	33	31	27	22	10	7	3	1
# of Rods	68	67	67	66	65	64	61	23	41	19	12	6	2
Average Percent Distraction Achieved	88.5%	89.8%	81.9%	79.6%	72.1%	67.3%	58.5%	57.3%	56.4%	54.5%	39.2%	55.6%	31.0%

Results - Radiographic Outcomes

	Mean Cobb Angle (All patients)	Mean Cobb Angle (Primary MCGR patients only)
Preoperative	56.6° ± 16.8	61.0° ± 16.6
Postoperative	38.4° ± 14.1	33.5° ± 11.6
2 years follow-up	41.6° ± 17.8	

$p < 0.001$ (Preoperative vs Postoperative for All patients)
 $p < 0.001$ (Preoperative vs Postoperative for Primary MCGR patients only)
 $p = 0.43$ (Postoperative vs 2 years follow-up for All patients)

	Mean T1-S1 Length
Preoperative	299.3 mm ± 48.1
2 years follow-up	351.2 mm ± 48.5
Change in T1-S1 Length	51.9 mm ± 28.1

$p < 0.001$ (Preoperative vs 2 years follow-up)

Complications

	# of Patients	# of Procedures (#/patient/year)	TGRs (#/patient/year)
Deep infection	2 (5.9%)	2 (0.02)	0.02 ¹ – 0.11 ²
Revision of fixation	8 (23.5%)	10 (0.12)	0.06 ¹ – 0.20 ²
ROH	2 (5.9%)	2 (0.02)	
Exchange of rod	1 (2.9%)	1 (0.01)	
Removal of rod	1 (2.9%)	1 (0.01)	
Revision of rod placement	1 (2.9%)	1 (0.01)	
Conversion to TGR	1 (2.9%)	1 (0.01)	
# of Unplanned Returns to OR	11 (32.3%)	17 (0.19/pt/yr)	0.10 ^{1,3} – 0.47 ²

¹Bess et al 2010

²Sankar et al 2010

³Teoh et al 2016

Conclusions

- The law of diminishing returns does appear to apply to MCGRs with a decrease in the percent distraction achieved over sequential lengthening sessions.
- MCGRs are effective at maintaining curve correction while allowing for spinal growth.
- Complications requiring an unplanned return to the OR occurred in 32.3% of our study patients, but the rate was comparable to TGRs.

References

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