

When and how to do distractions with MCGR

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SAN DIEGO CENTER
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Disclosures (Growing Spine)

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Distraction Based Treatment Options

- Traditional Growing Rods
 - Require surgical procedure to lengthen the rods
- VEPTR (Vertical Expandable Prosthetic Titanium Rib)
 - Require surgical procedure to lengthen the construct
- MAGEC System
 - Non-invasive distraction eliminates repeated surgeries for lengthening



TGR/VEPTR Distractions

- Repeat **Open lengthenings** usually every 6 months and some evidence that can go shorter or longer based on age and diagnosis
- Repeated **Anesthesia, Neuromonitoring**
- Increased Risk Of Complications (e.g., infection)
- May Require Overnight **Hospitalization** (ICU)
- May be **traumatic event** for children



The MCGR Distraction

- No open surgery
- No **anesthesia**
- No overnight hospitalization
- Minimal **time loss** for child and parents and less stressful
- Patients report **no pain**
- More **frequent distractions** possible



MCGR: When and How?

- **When:** When to start and how frequently?
- **How:** Maximum force vs targeted displacement



Answer?

- **We don't know**



What we know

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■ Dual Growing Rod Technique for the Treatment of Progressive Early-Onset Scoliosis

A Multicenter Study

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Alistair G. Thompson, FRCS,† and Marc A. Asher, MD§

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■ Comparison of Single and Dual Growing Rod Techniques Followed Through Definitive Surgery

A Preliminary Study

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Connie Poe-Kochert, CNP,* Douglas G. Armstrong, MD,* Jeffrey Roh, MD,‡
Robert Lowe, MD,‡ Marc A. Asher, FRCS,§ and David S. Marks, MD||

Better correction and growth with more frequent distraction resulted in a practice of 6 months lengthening intervals





Is There an Optimal Time to Distract Dual Growing Rods?

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Study Design: Retrospective multicenter observational cohort study.

Objectives: To determine whether there is a significant difference in final spinal height achieved, instrumented height, or Cobb angle related to the mean time interval between distractions of dual growing rods.

Summary of Background Data: Patients were prospectively enrolled in “The Treatment of Progressive Early Onset Spinal Deformities: A Multi-Center Study.” Additional data were collected via a retrospective review of medical records.

Methods: Using data from a multicenter database, the authors identified 46 patients (23 boys and 23 girls) with early-onset scoliosis who were treated with dual growing rods and who had surgical treatment spanning more than 4 years. The patients were divided into 2 groups: those who had less than 9 months (16 patients) and those who had 9 months or more (30 patients) between distractions. Standard univariate statistics were calculated. The researchers performed 2-tailed *t* tests. Significance was set at $p = .05$.

Results: The differences in primary Cobb angle, T1–S1 height, and instrumented segment length at the last distraction or final arthrodesis, compared with the post-index procedure values, were not significantly different ($p = .52, .58, \text{ and } .60$, respectively) between groups with the available data. The normalized instrumented height gains, in millimeters per year, were not significantly different ($p = .22$).

Conclusions: Patients with longer times between growing-rod distractions (9 or more months) had no significant differences in primary Cobb angle, T1–S1 length, or instrumented length gain compared with patients with shorter times (less than 9 months) between distractions.

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Rod Fracture and Lengthening Intervals in Traditional Growing Rods: Is There a Relationship?

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Boston, MA, USA**



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Results

INTERVALS (months)											
	1st	2nd	3rd	4th	5th	6th	7th	8th	9th	10th	11th
NRF	8	8.64	9.23	9.77	9	8.15	11.3	9.79	6.74	7.59	-
RF	8.16	8.26	8.06	7.88	9.06	8.39	10	6.46	6.77	9.33	14.3

P > 0.05



Conclusion

- Lengthening intervals were not statistically different in RF and NRF groups. Hence, shorter lengthening intervals (**more frequent lengthenings**) should not benefit the traditional dual growing rods in terms of rod fracture prevention.
- Patients who had rod fracture **were younger** at the time of index surgery and had more SS rods.



FEA Model for Frequent Distraction

**Spine
Deformity**

www.spine-deformity.org



Spine Deformity 2 (2014) 430–436

Biomechanics

Smaller Interval Distractions May Reduce Chances of Growth Rod Breakage Without Impeding Desired Spinal Growth: A Finite Element Study

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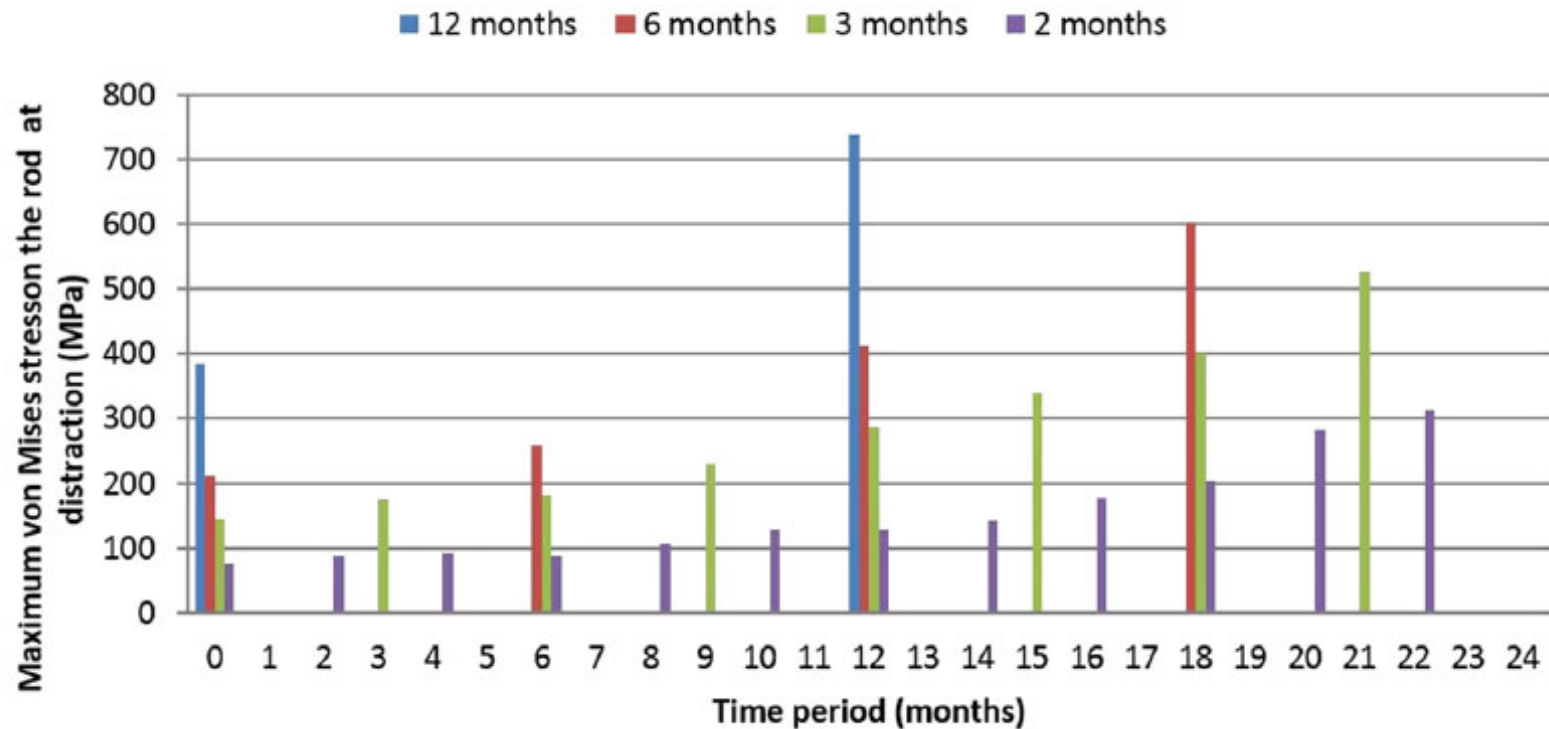
Received 6 May 2014; revised 5 August 2014; accepted 8 August 2014



FEA Results

Results: The stresses on the rods were highest for 12-month distraction (2 distractions in 2 years) and lowest for 2-months distraction (12 distractions in 2 years).

Conclusion: It was found that the shorter intervals of distraction led to reduction of stresses on the rod for same spinal height gain in two years.



MCGR and frequency of lengthenings

Effects of frequency of distraction in magnetically controlled growing rod lengthening on outcomes and complications

Kenneth MC Cheung, Kenny Kwan, Dino Samartzis, Karen KL Yiu, Ahmet Alanay, John Ferguson, Colin Nnadi, Ilka Helenius, Muharrem Yazici, Gokhan Demirkiran, Behrooz Akbarnia



Results and conclusion

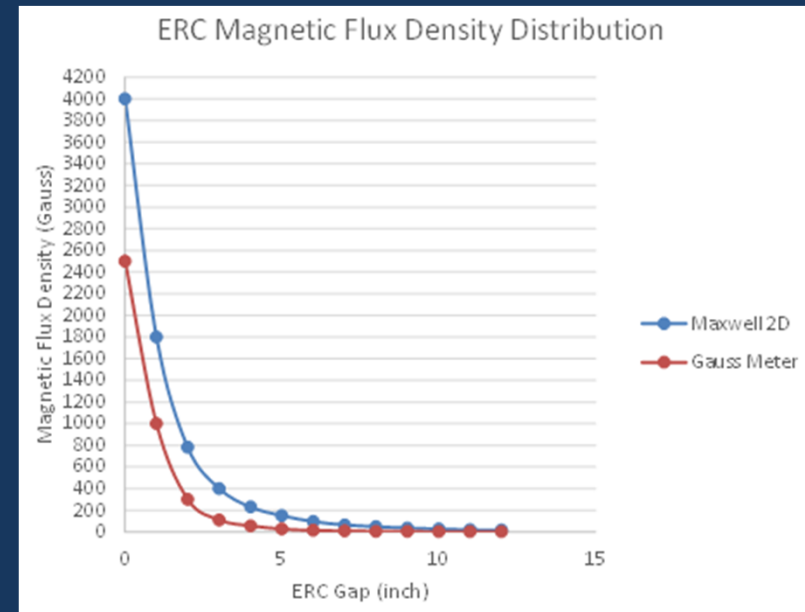
- More frequent distraction were associated with increased incidence of rod distraction failure and proximal junctional kyphosis but lower incidence of implant-related complications. Clinicians should be aware of potential higher risk for re-operation if the interval between each distraction is less than 3 months.



Magnetic Force

Magnetic Force

- Magnetic field strength decreases exponentially with distance.



- Engagement between ERC and device magnet is not binary
 - **It is a not an “on/off” condition.**
- Distraction force is proportional to ERC/device engagement.
 - **The closer the ERC, the higher the distraction force.**



Distraction Techniques

- Max Force
 - Driving Growth
 - Distract until stall: multiple stalls will provide max force
- Targeted Displacement
 - Keeping up with Growth
 - Dial in the desired amount into ERC



Distraction at surgery



MAGEC Distraction Technique

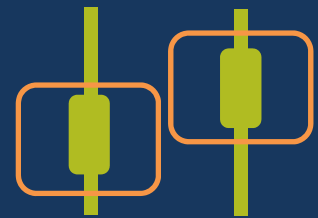
- Coupled Distraction

- Standard/Standard rod configuration with the MAGEC ERC anatomically centered and in continuous mode



- Independent Distraction

- Standard/Offset rod configuration with the MAGEC ERC centered over each rod actuator




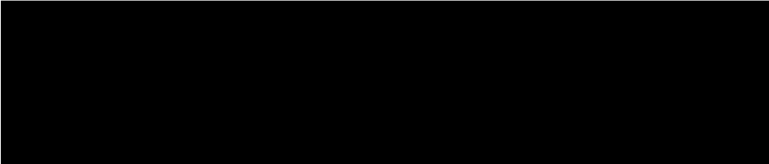

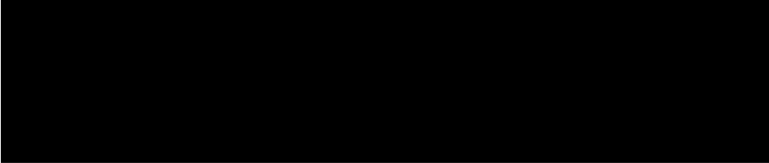
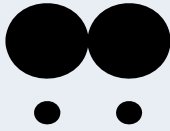

MAGEC Distraction Forces

- Single MAGEC Rod
 - 44 lbs. of force generated
- Dual MAGEC Rod Standard/Standard
 - Approx. 90 lbs. of force generated
- Dual MAGEC Rod Standard/Offset
 - Approx. 90+ lbs. of force generated



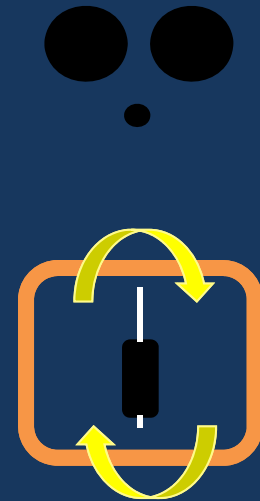
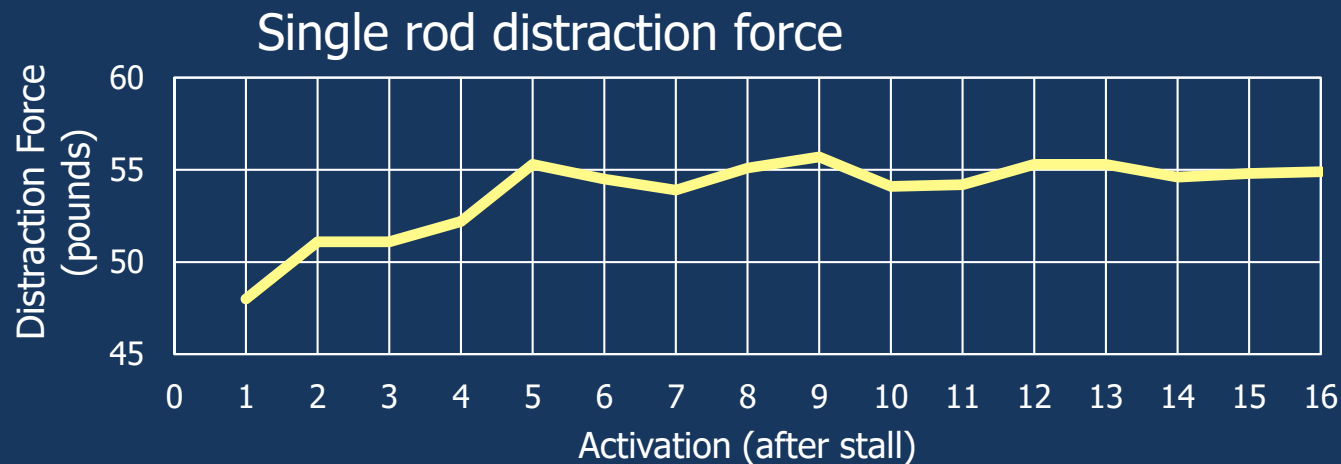
Techniques

Goal: Determine maximum force of rod and ERC distraction configurations

Rod(s)	Distraction configurations	
	ERC centered between rods	ERC centered over actuator
Single rod		
Dual rod: Standards		
Dual rod: Standard, Offset		



Performance

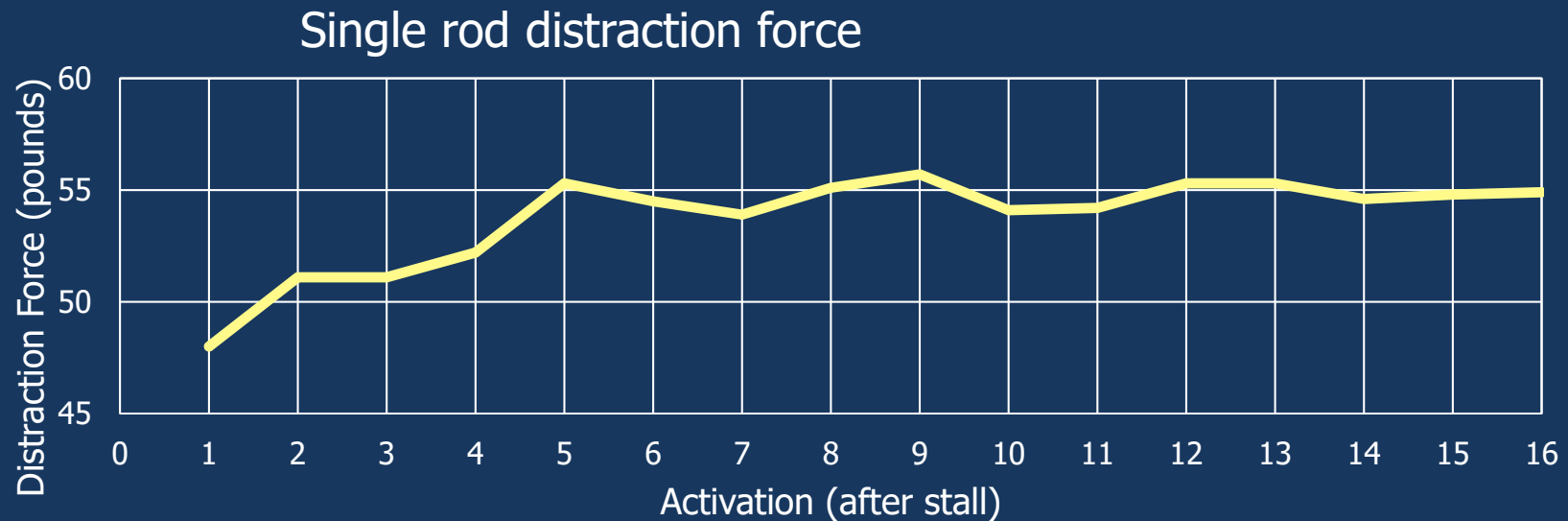


Stall

- **What:** Inability of the ERC to turn the device magnet.
- **Why:** Device cannot overcome anatomical forces of the spine (spine flexibility, growth, coupling with the ERC).
- **How:** Sensory (audible, tactile) feedback.
- **Note:** Not a negative event, rather, (1) a tool for achieving more incremental force and (2) appropriate governor of force output.



Performance

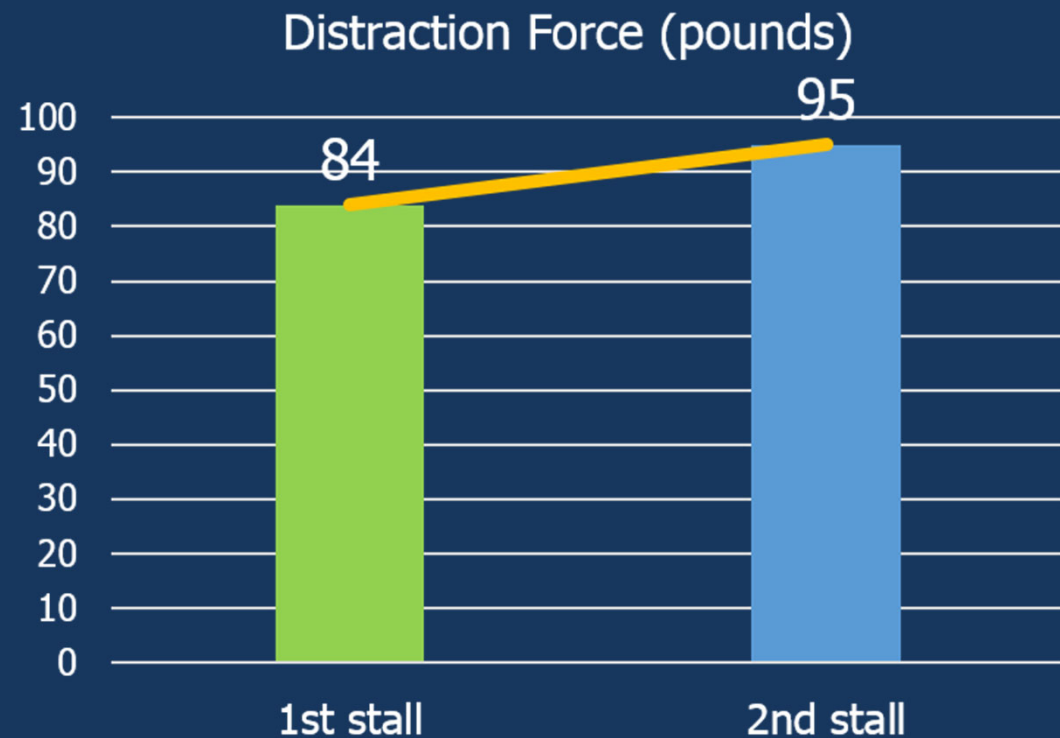
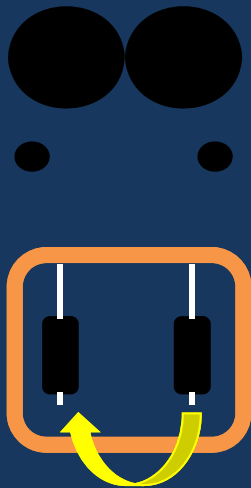


Repeated distraction attempts
increases distraction force.



Distraction force

- Standard dual rod configuration
- Two total activations
- Centered between rods

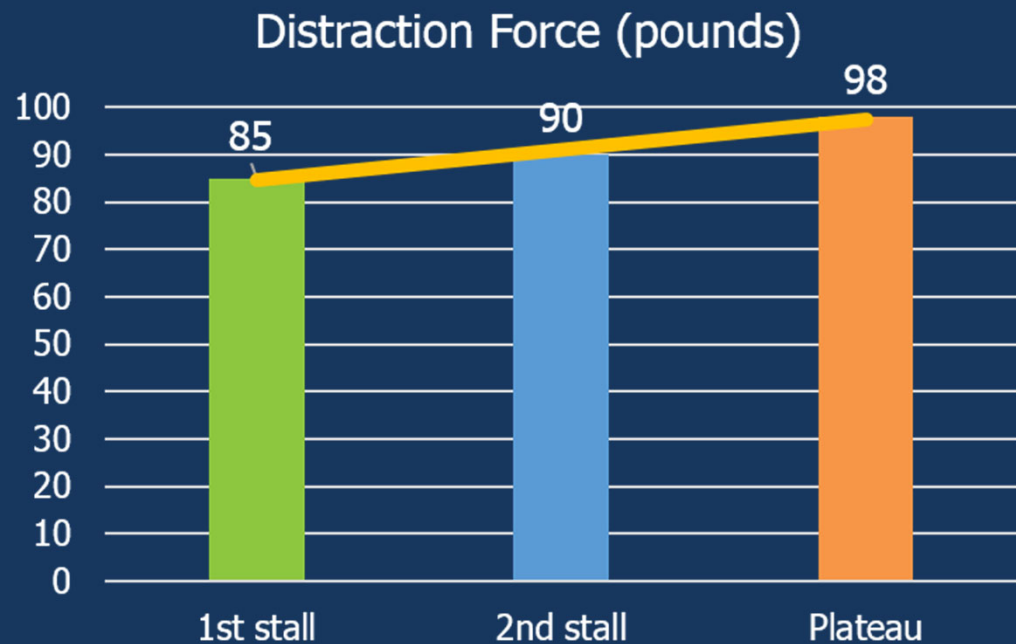


- Rods are driven simultaneously
- Repeated activations increase distraction force



Distraction force

- Standard dual rod configuration
- 20 total activations
- Centered over each actuator

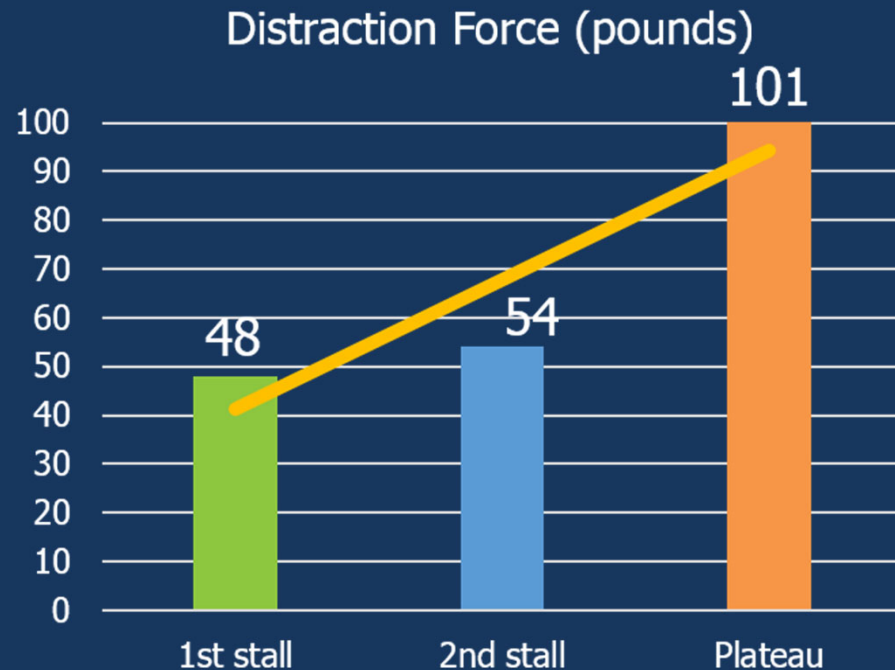
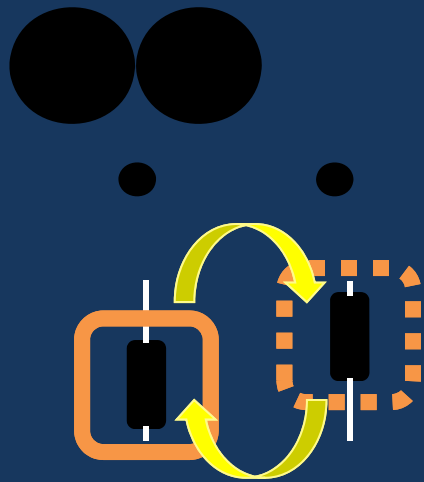


- Multiple cycles of repeated activations increases distraction force



Distraction force

- Standard and offset dual rod configuration
- 20 total activations
- Centered over each actuator



- Multiple cycles of repeated activations greatly increases distraction force
- Independent distraction of each rod can be achieved



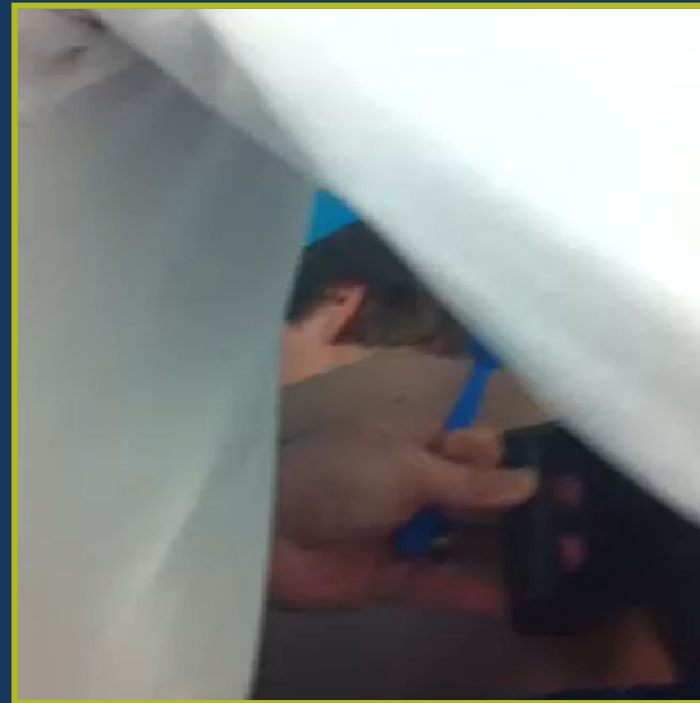
Distraction Frequency

- Monthly
 - Targeted Displacement
 - 1 – 2 mm
- Every 2 - 4 months
 - Targeted Displacement or Max Force
- Every 6 months
 - Max Force



Our Technique at Rady Children's

- Every 2-3-months with a targeted displacement protocol
 - Our rod configuration is Standard/Standard



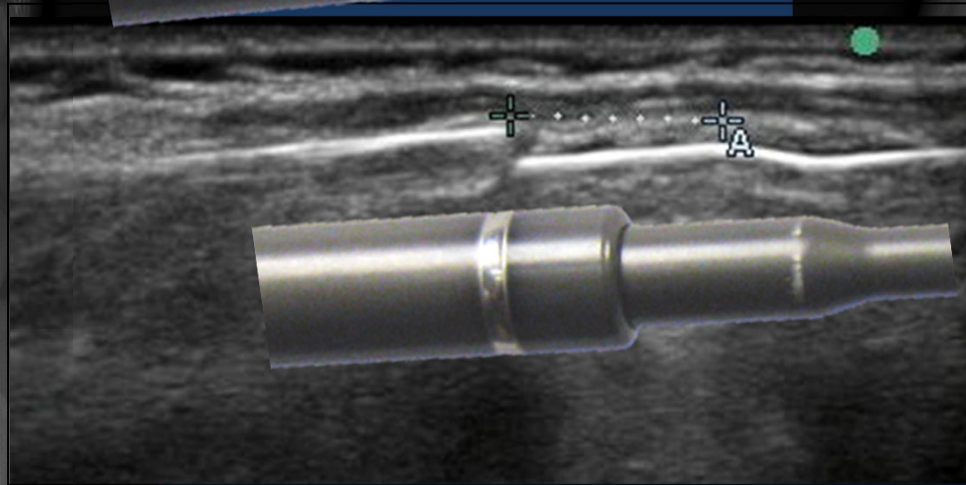
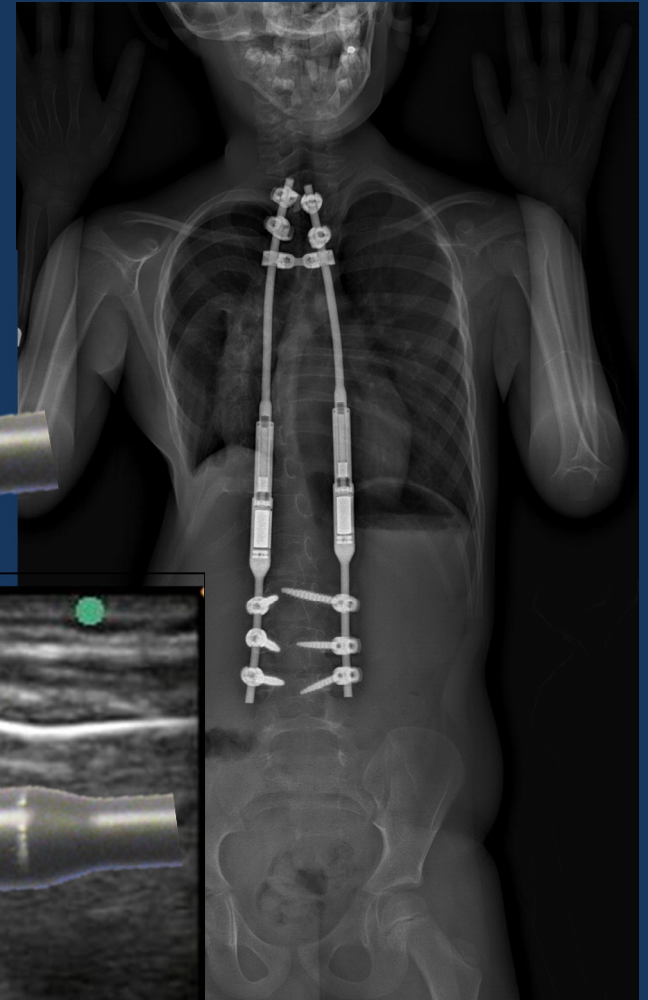
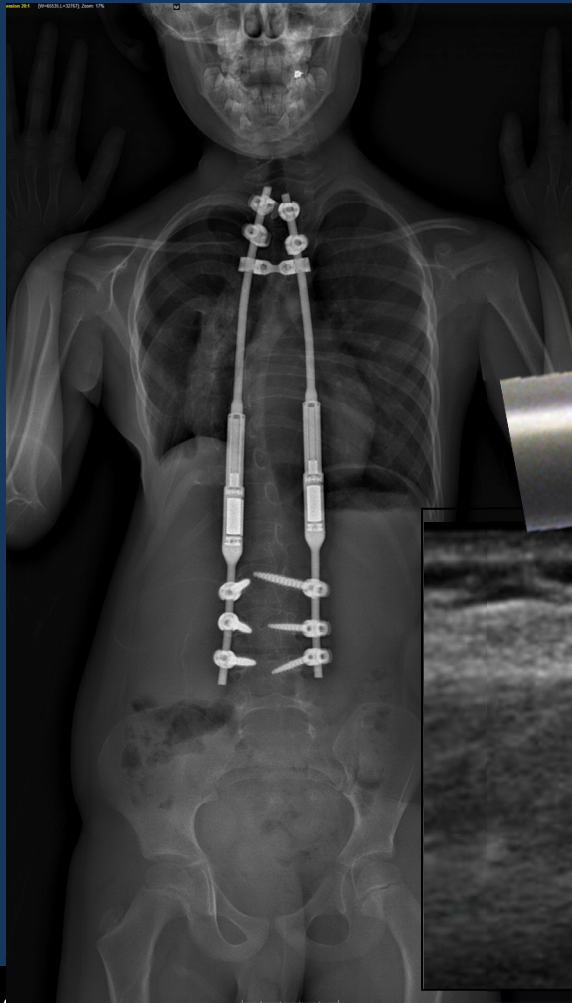
Lengthening with Ultrasound



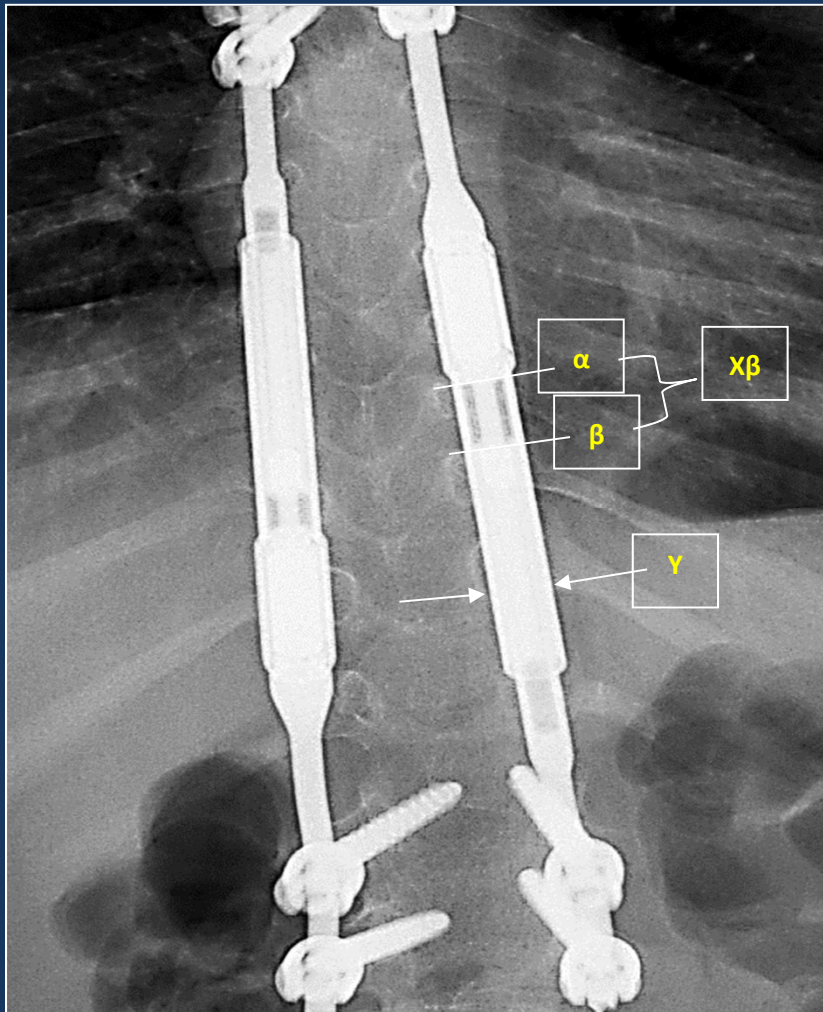
Mark the skin so that the KY doesn't prevent you from doing so later



Ultrasound Evaluation



Calibration



Calibration = $9.02 / \gamma$

Total distraction amount =
 $x \cdot \text{Calibration}$



Template for Epic

Name: Santiago Anaya Inchaurrendieta
Date of visit: 11/16/2015
Historian: {Historian:23189}

Diagnosis:
1. S/P spinal fusion XR Spine TL 1 View
XR Spine TL 1 View

Reason for today's visit: Lengthening of MAGEC

HISTORY:
Santiago is a 9 y.o. male, with a history of {Scoliosis hx:28179}. On *** he underwent placement of magnetically controlled growing rods, and now returns for routine #*** lengthening. He denies having symptoms of numbness, tingling, weakness or bowel/bladder incontinence. He reports {Pain:2101110714: "no significant back pain"}. He has had no fevers and reports no shortness of breath.

Past Medical History
Diagnosis: Obesity Date: 10/3/2013

No past surgical history on file.

I have reviewed Santiago's past medical and surgical history, review of systems, family and social history as documented in the electronic medical record.

PHYSICAL EXAM:
There were no vitals taken for this visit.

His back examination demonstrates {severity:2101110710: "minimal"} trunk deformity. His incision is {incision:2101110706: "well healed with a flat scar"}.

Reflexes are {ORT Reflex:28180} bilaterally at the knees and ankles, down-going Babinski bilaterally.

Gait: {Gait ortho:28230}.

Motor: {motor ortho:28231}.

ATR1: {numbers free 1-10:28229} degrees, {ATR:28232}, {RIGHT/LEFT LOWER CASE:24813}
ATR2: {numbers free 1-10:28229} degrees, {ATR:28232}, {RIGHT/LEFT LOWER CASE:24813}

RADIOGRAPHS:
No results found.

PROCEDURE: Lengthening of growing rods, with ultrasound assistance.
After obtaining consent for the procedure, the patient was positioned prone and prepped for lengthening. A time out was called prior to proceeding with the lengthening, in accordance to RCHSD policy. Ultrasound was then utilized to demarcate the area to be studied for lengthening. The magnetic apparatus was then utilized in the form of the external remote controller. The MCGR was then lengthened {ortho spontaneous:28233}.

Planned distraction: Left=#{numbers free 1-10:28229}, Right=#{numbers free 1-10:28229}
Actual distraction: Left=#{numbers free 1-10:28229}, Right=#{numbers free 1-10:28229}

The patient tolerated the procedure well. Santiago remained neurologically intact throughout and following the lengthening.

IMPRESSION: 9 y.o. male, with a history of {Scoliosis hx:28179} s/p MAGEC placement and now with #*** lengthening, doing well.

PLAN:

- We are happy with Santiago's progress thus far.
- We will therefore see Santiago back to the Early Onset Scoliosis Clinic in {NUMBERS 1-12:18279} months for repeat lengthening.
- If the family has any concerns or questions in the interim, we ask that they contact our Early Onset Scoliosis Clinic.

Accept Cancel
Name Dose, Route, Frequency Patient Sig



Summary MCGR Distraction

- Need to **build consensus** and **develop practice guidelines** for non-invasive distractions to reduce surgeon variability and improve reproducibility
- Maximum force can be achieved through multiple distraction cycles (10-20 stalls).
- Dual rod standard, offset construct with multiple cycles (ERC alternating above each actuator) achieves **highest max force**.
- Dual rod standard construct with the ERC centered between rods can achieve comparable distraction forces while allowing **coupled** (simultaneous) distraction of each rod.
- Dual standard/offset construct with the ERC alternating above actuators seems to be the best method to provide **independent** distraction of each rod.



Thank You

