

MCGR- WHEN IS IT **NOT** INDICATED?

Gregory M Mundis, Jr., MD
Scripps Clinic Medical Group
Rady Children's Hospital
San Diego, California

9th ICEOS Boston, MA



San Diego
Spine Foundation



DISCLOSURES

◎ **CONSULTING:**

1. **Ellipse**
2. Nuvasive
3. Medcrea
4. Misonix
5. K2M

◎ **Royalties:**

1. Nuvasive
2. K2M

◎ **Research Support**

1. Nuvasive
2. DePuy

Complications of Growing-Rod Treatment for Early-Onset Scoliosis

Analysis of One Hundred and Forty Patients

By Shay Bess, MD, Behrooz A. Akbarnia, MD, George H. Thompson, MD, Paul D. Sponseller, MD, Suken A. Shah, MD,
Hazem El Sebaie, FRCS, MD, Oheneba Boachie-Adjei, MD, Lawrence I. Karlin, MD, Sarah Canale, BS,
Connie Poe-Kochert, RN, CNP, and David L. Skaggs, MD

Investigation performed at San Diego Center for Spinal Disorders, La Jolla, California *JBJS, December 2010*

- ⊙ **Growth modulation with current Growing Rod (GR) techniques require frequent surgical lengthenings and are associated with high risk of complications**
- ⊙ **The complication risk increased by 24% for each additional surgical procedure.**
- ⊙ **Goal of remotely controlled devices: To reduce frequency of surgeries**

Traditional Growing Rods Versus Magnetically Controlled Growing Rods for the Surgical Treatment of Early-Onset Scoliosis: A Case-Matched 2-Year Study

- In this small yet carefully matched series, **major curve correction was similar** between MCGR and TGR patients throughout treatment
- MCGR patients had **52 fewer surgical procedures** than TGR patients
- While curve correction was similar, **annual T1-S1 growth was 3.5 mm/year greater in TGR patients** compared to MCGR patients

IMPLANT COMPLICATIONS AFTER MAGNETIC-CONTROLLED GROWING RODS FOR EARLY ONSET SCOLIOSIS: A MULTICENTER RETROSPECTIVE REVIEW

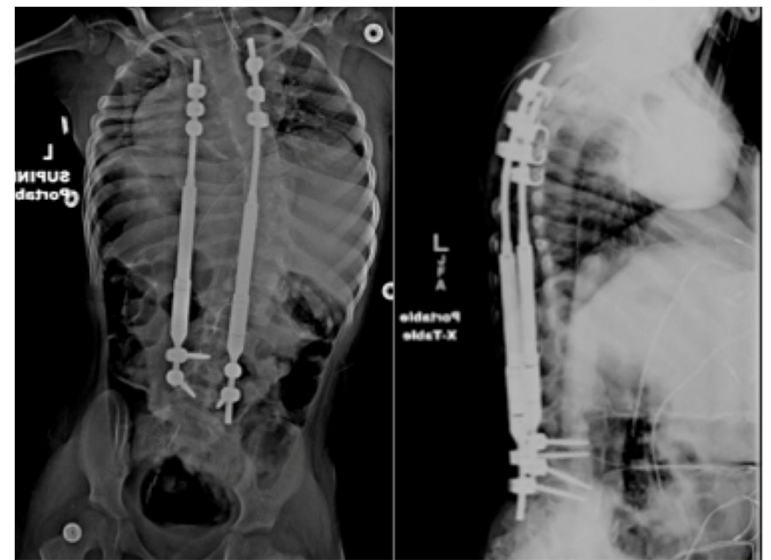
- ⊙ **Complications (COMP) were categorized as wound-related and instrumentation-related.**
- ⊙ **COMP were also classified as early (< 6 months) versus late.**
- ⊙ **Distraction technique and interval of distraction was surgeon preference without standardization across sites**

RESULTS

- ⊙ **21 of 54 patients had at least 1 COMP**
- ⊙ **15/21 of those had revision surgeries.**
- ⊙ **6 had broken rods**
 - ⊙ 2- 4.5 and 4- 5.5 mm rods
 - ⊙ 2/4 5.5 mm rods failed early (4 mo) and 4 late (mean = 14.5 mo).
- ⊙ **6 experienced 1 episode of lack or loss of lengthening of which 4 lengthened subsequently.**
- ⊙ **7 had either proximal or distal fixation-related CMP at avg of 8.4 mo.**
- ⊙ **2 had infections requiring I&D, one early (2 wks) with wound drainage and one late (8 mo).**
 - ⊙ The late case required explantation of one of the dual rods

CONCLUSION

- ⊙ There is a low infection rate (3.7%) with MCGR
- ⊙ MCGR does not appear to prevent common implant related complications such as rod or foundation failure.
- ⊙ The lack of lengthening seen at some visits is unique to MCGR.
 - ⊙ The long term implication of this remains to be determined



COMPARISON OF PRIMARY VS. CONVERSION SURGERY WITH MCGR RODS IN CHILDREN WITH EOS

- ⊙ 27 Primary (mean age 7.0 ± 2.2 years at surgery)
- ⊙ 23 C patients (mean age 7.7 ± 2.4 years)
- ⊙ P underwent mean 8.0 ± 5.5 and C 3.5 ± 2.4 lengthening's at last follow-up ($p=0.0006$)
- ⊙ 22 patients having a minimum 2-yr FU (mean FU time 22.4 ± 7.9 months for P and 17.3 ± 5.9 for C, $p<0.05$)

RESULTS

| | De novo (n=27) | Conversion (n=23) | p |
|-----------------------------------|-------------------|----------------------|--------|
| Major Cobb°,mean(SD) | | | |
| Baseline | 64 (18) | 47 (16) | 0.0009 |
| Postoperative | 35 (15) | 36 (18) | 0.80 |
| 1-yr FU | 40 (17) | 40 (19) | 0.99 |
| T1-S1 height, mm,mean (SD) | | | |
| Baseline | 265 (46) | 273 (27) | 0.43 |
| Postoperative | 308 (44) | 286 (31) | 0.09 |
| 1-yr FU | 311 (47) | 290 (49) | 0.18 |
| Change from baseline at 1-yr FU | 18 (14) | 6.5 (8.4) | 0.007 |

⊙ COMPLICATIONS:

- ⊙ 8 patients needed surgical intervention (29.6 %) in P and 7 (30.4 %) in C (p=0.95). 1 patient in C developed a deep wound infection.

CONCLUSIONS

- © **Satisfactory** correction can be achieved with **primary** MCGR and **maintained** following **conversion** to MCGR
- © **Spinal growth** with subsequent non invasive lengthenings is **less in conversion** patients compared to **primary**

WHEN IT'S **NO** GOOD

⊙ **IMPLANT SPECIFIC**

- ⊙ Need for repeat MRI
- ⊙ The actuator is too large
- ⊙ Financial investment

⊙ **PATIENT RELATED**

- ⊙ Severe kyphosis
- ⊙ Large curves?
- ⊙ Stiff curves?
- ⊙ Conversion patients

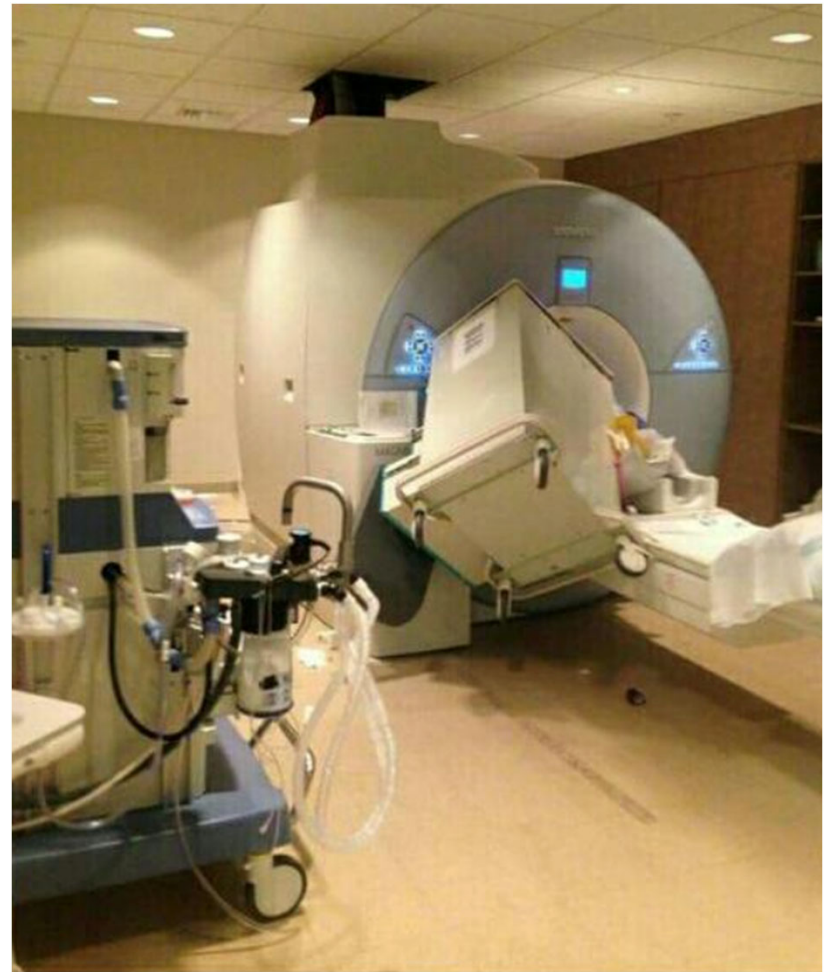
⊙ **SOCIAL**

- ⊙ Insurance issues
- ⊙ Hospital approval of device
- ⊙ Patient travel

IMPLANT SPECIFIC- MRI

⊙ Patients with medical conditions that require repeat MRI

- ⊙ Tumor
- ⊙ Other intraspinal conditions
- ⊙ Myelopathy
- ⊙ Occipital cervical pathology
- ⊙ Other Medical conditions



**When you forget that MRIs
are giant magnets...**

Safety and compatibility of magnetic-controlled growing rods and magnetic resonance imaging

Henry R. Budd¹ · Oliver M. Stokes¹ · Judith Meakin² · Jonathan Fulford³ · Michael Hutton¹

◎ METHODS

This is an in vitro experiment using two magnetic growth rods secured in a 1.5 T MRI. A gradient echo sequence MRI was performed to evaluate whether the rods elongated, contracted or rotated during scanning and a phantom model was used to evaluate the amount of artifact induced.

◎ CONCLUSION

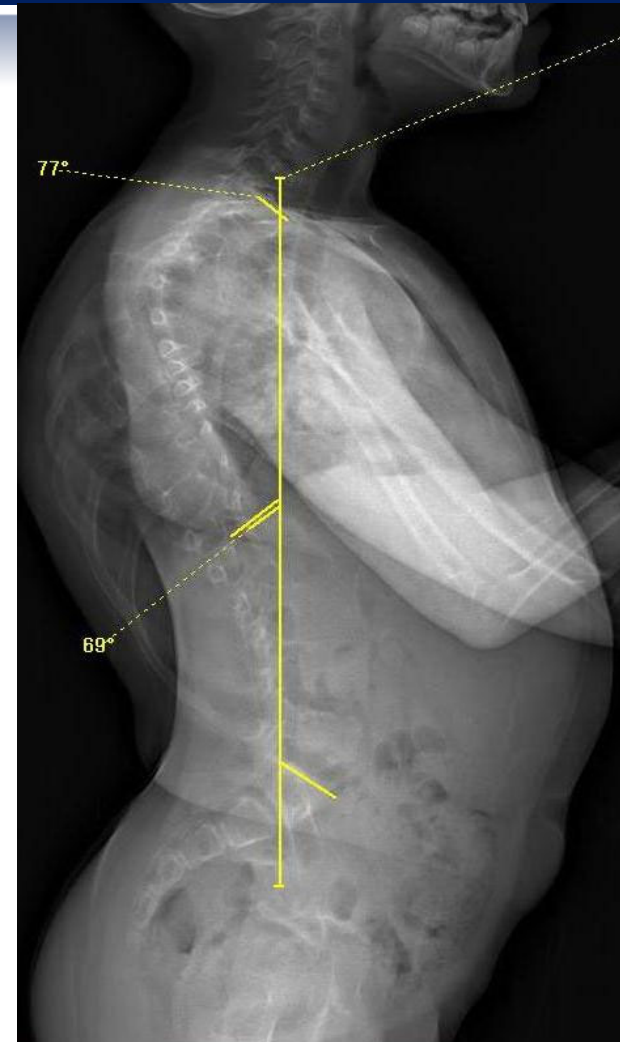
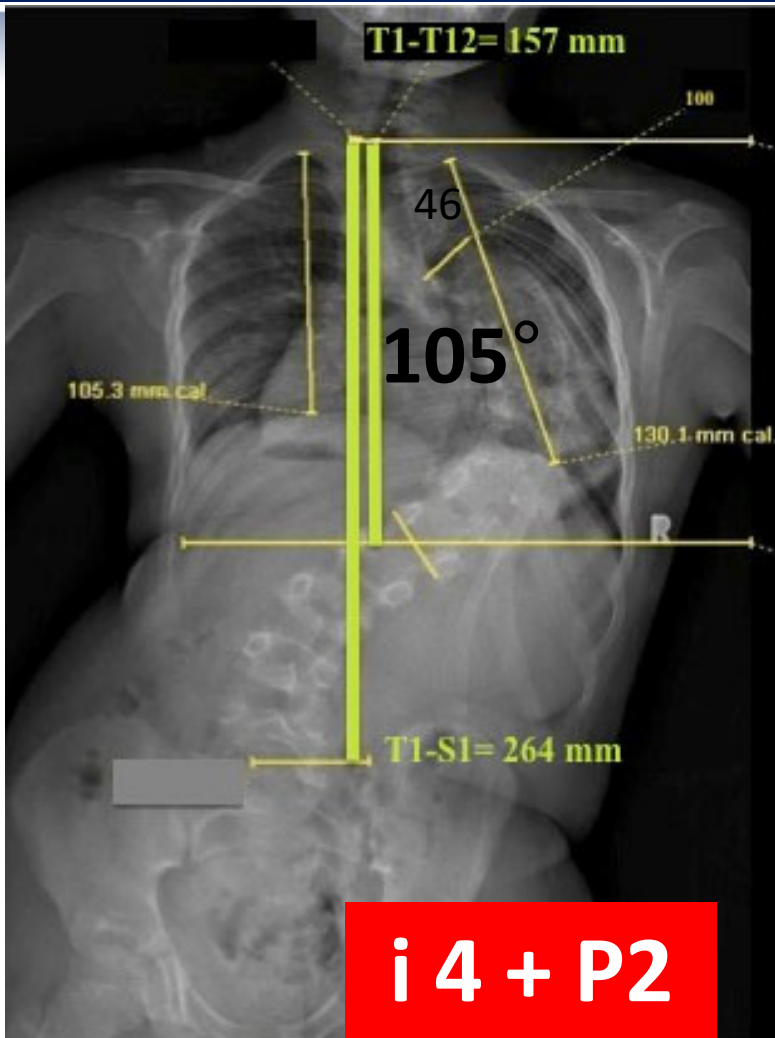
This study has demonstrated that **there are no detrimental effects of MRI on the MCGR** and imaging of the head and neck phantom can still be interpreted. Further in vivo study is warranted.

IMPLANT- THE ACTUATOR IS TOO LARGE

- ⊙ There are curves amenable to MCGR treatment however the size of the actuator limits its utility
 - ⊙ 70 and 90 mm
 - ⊙ Has to be planned before surgery
 - ⊙ Very young children and those affected by short stature

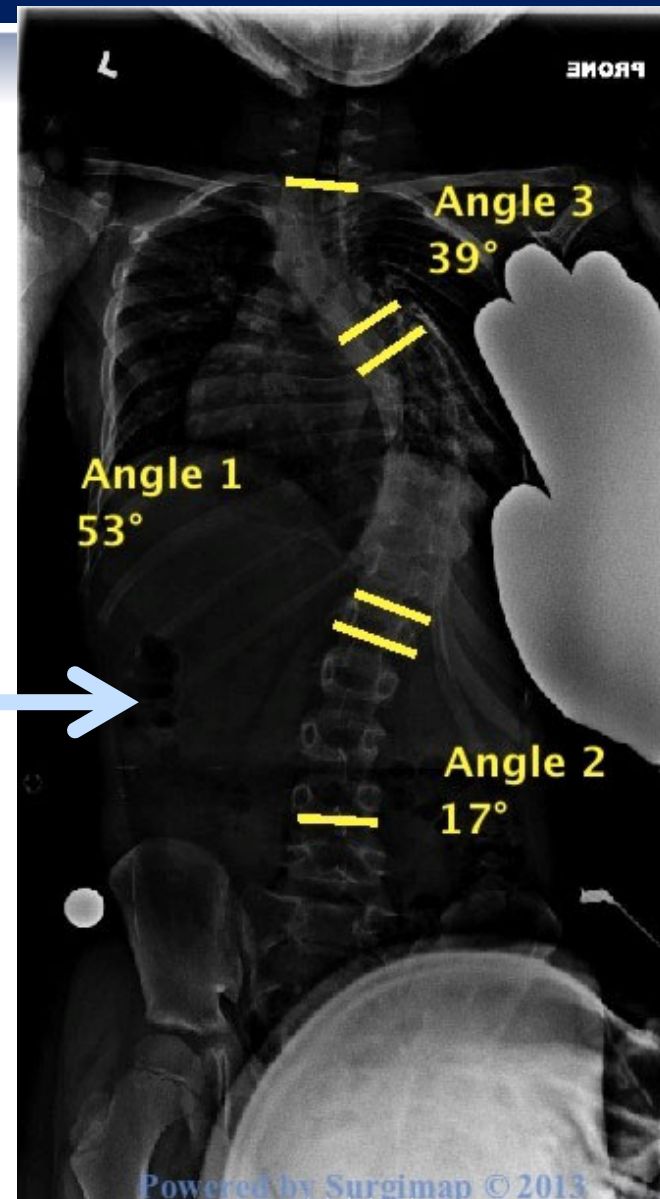
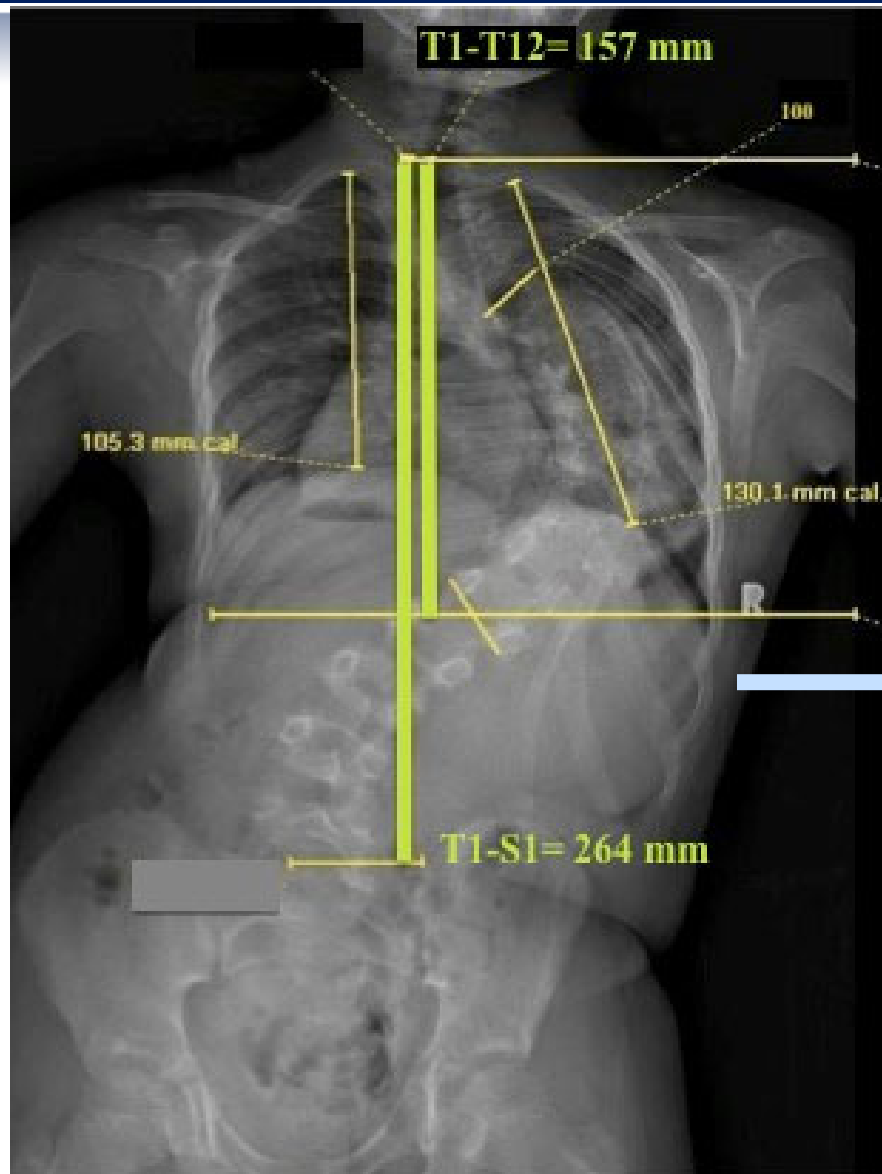


PATIENT FACTORS

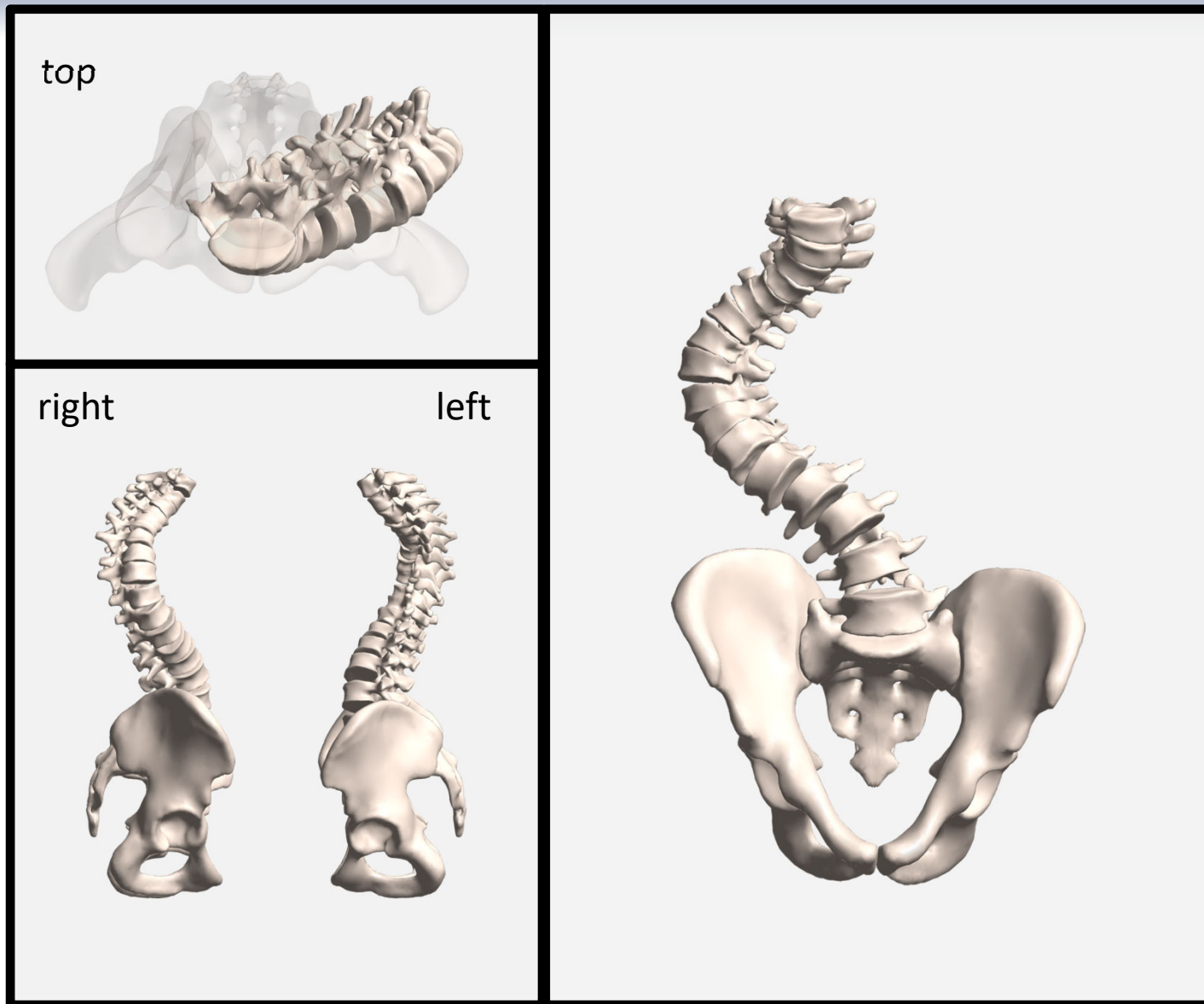


Major Cobb (T5-L1)= 105°, T1-T12 height= 157 mm, T1-S1 height= 264 mm
SAL ratio= 0.81, Lumbar lordosis= 69°, Thoracic kyphosis= 77°

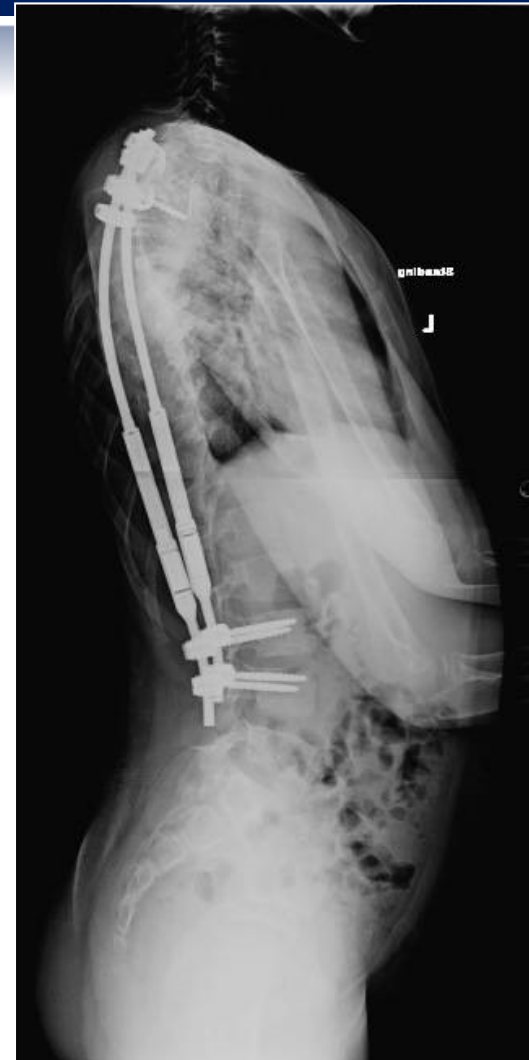
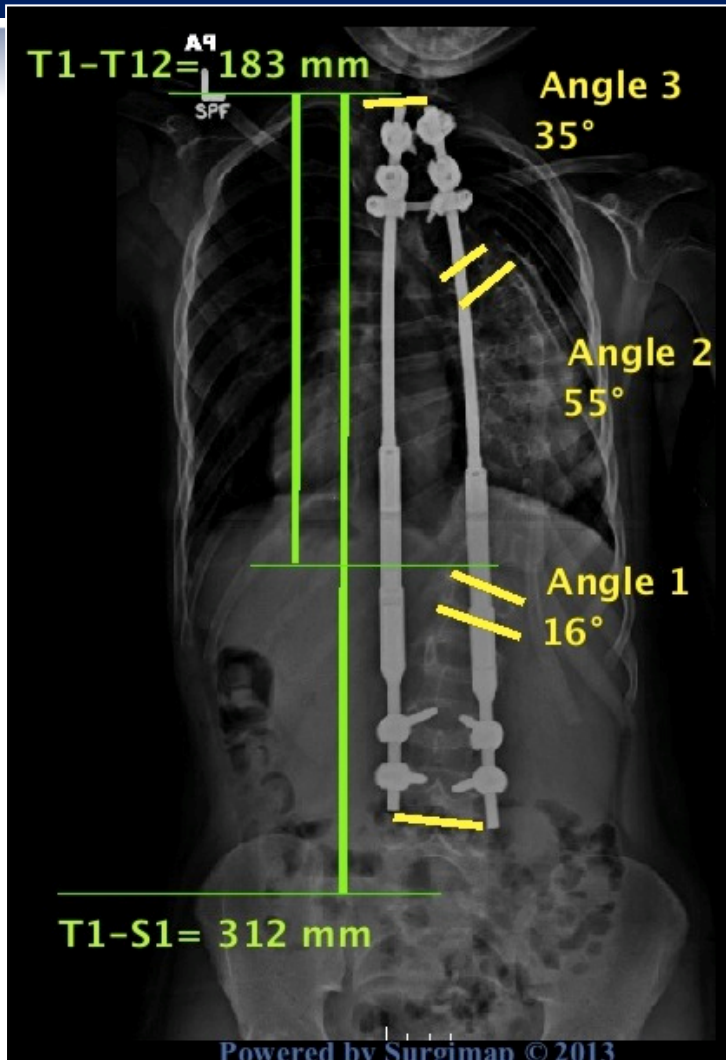
PUSH PRONE



PRE OPERATIVE

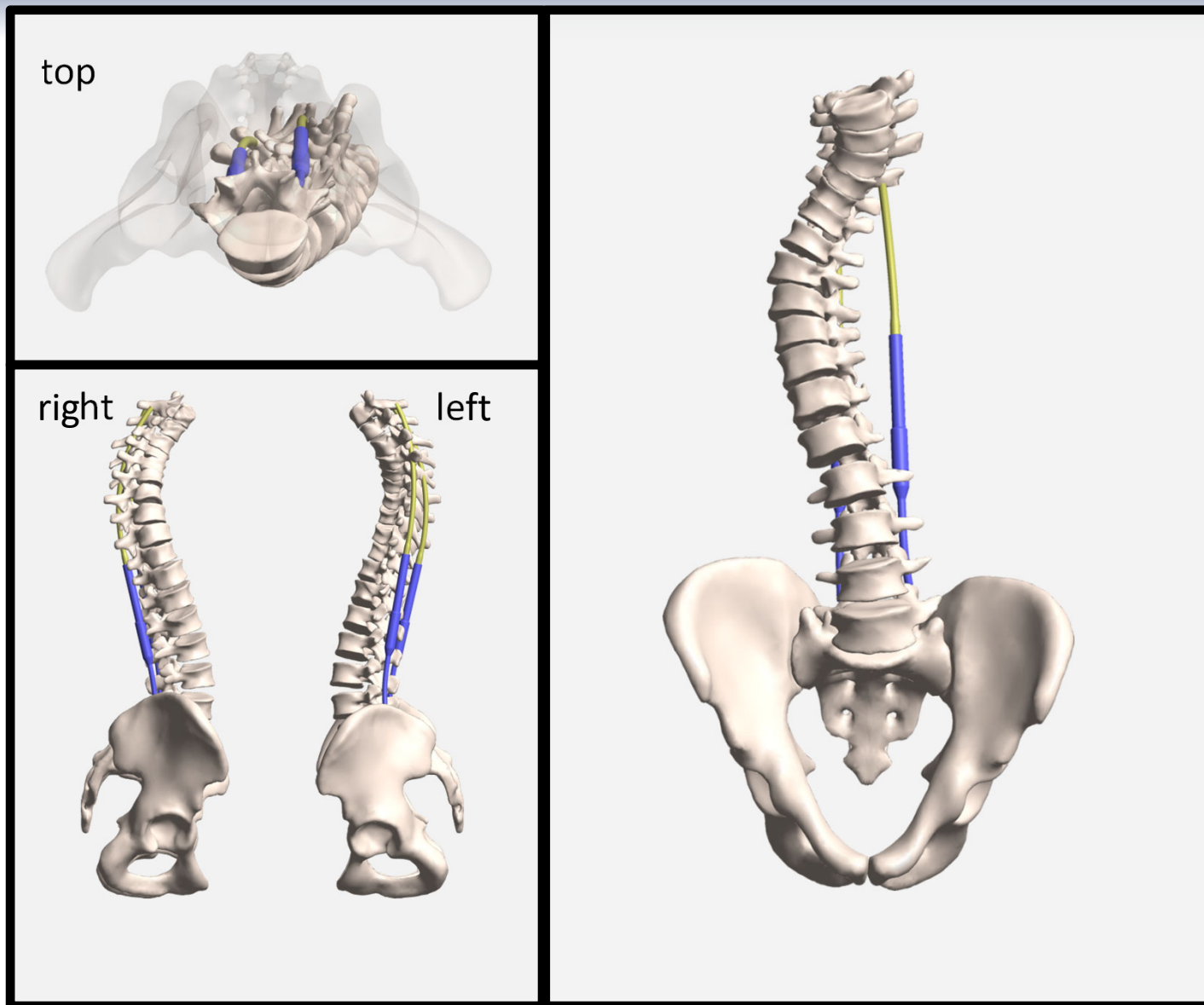


MAY 2013: Post-op X-Rays

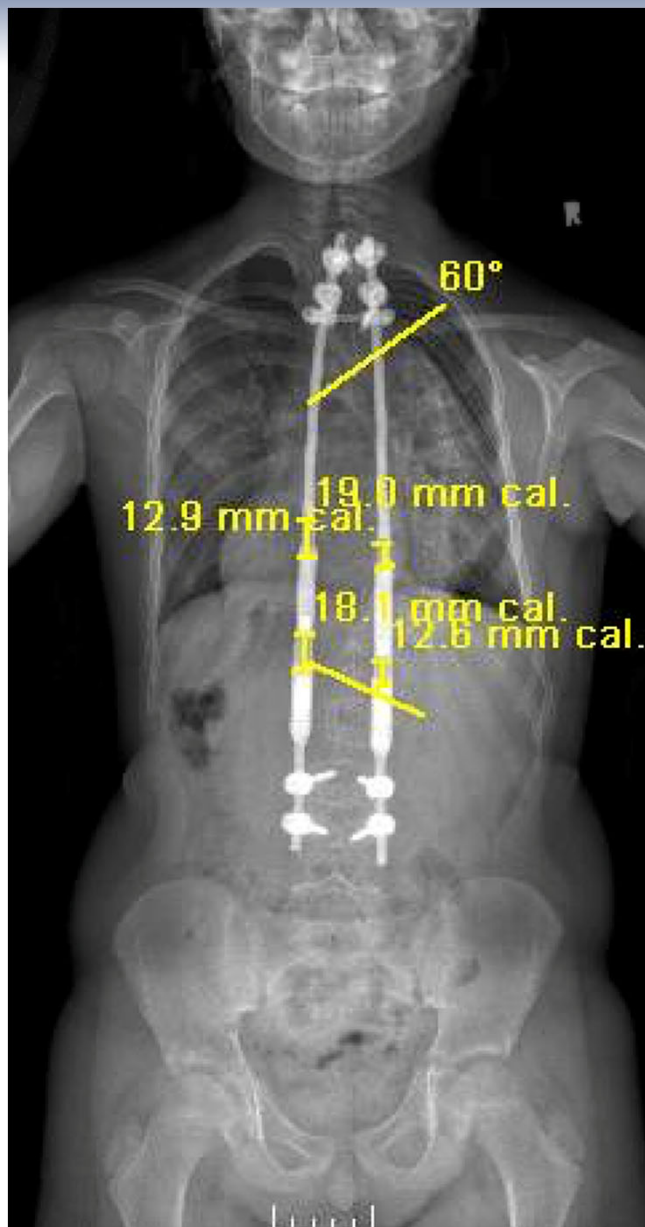


Major Cobb (T6-L1) = 55°, T1-T6 = 35°, L1-L4 = 16°
T1-T12 height = 183 mm, T1-S1 height = 312 mm

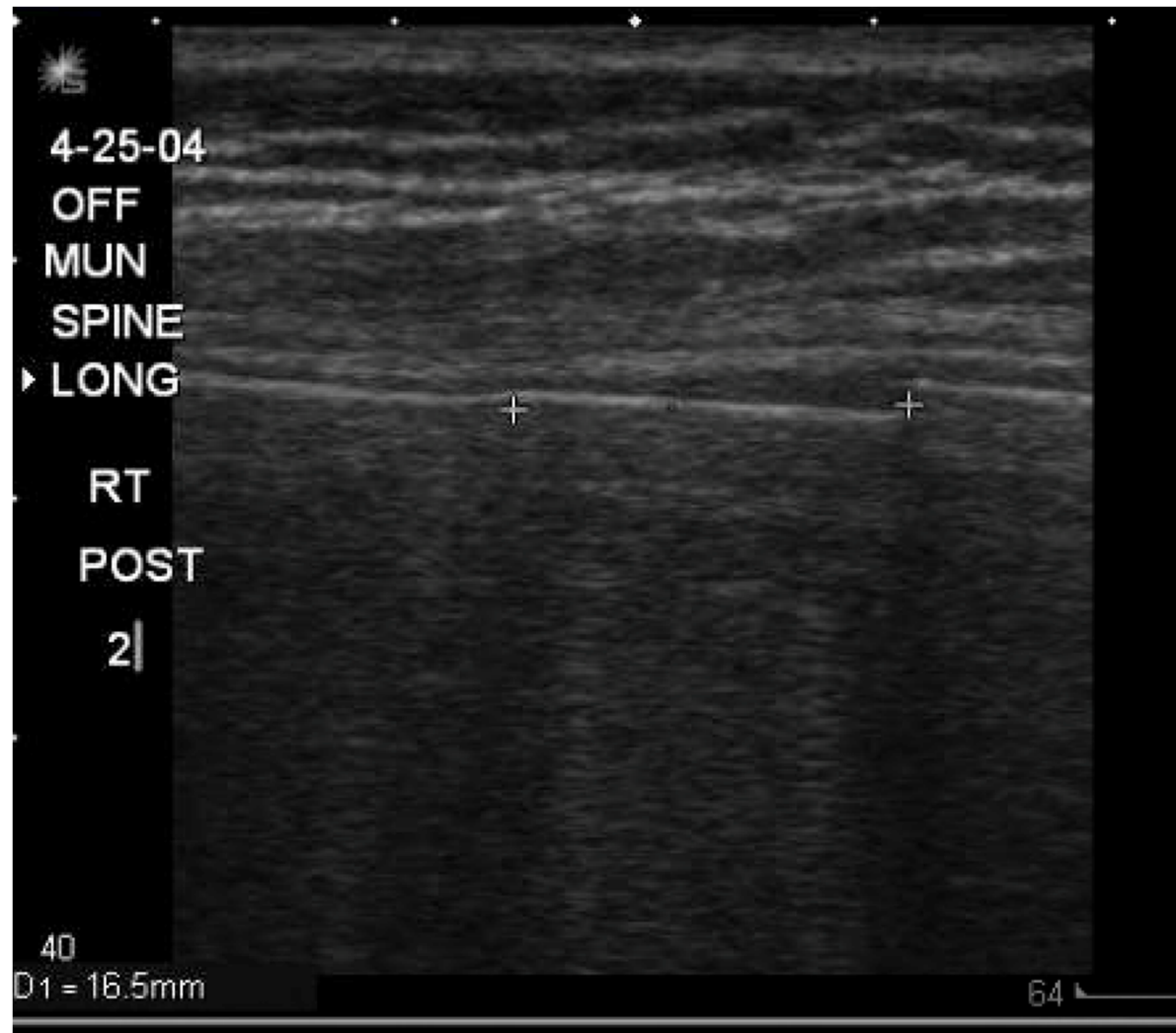
POST OPERATIVE



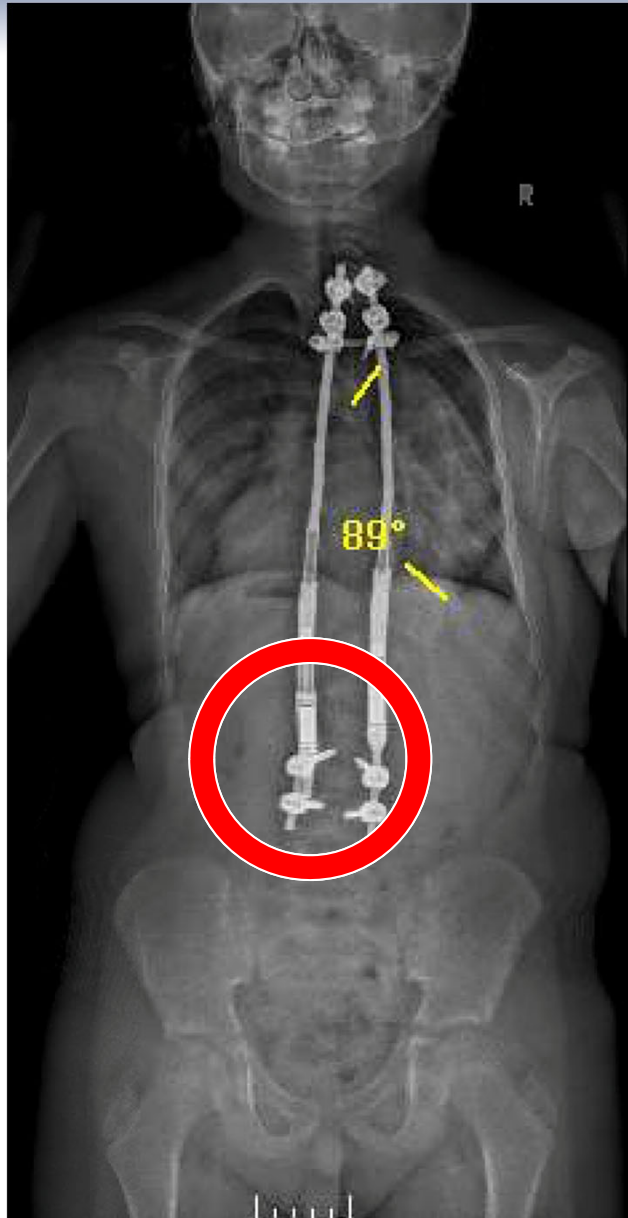
S/P 3 NON-OPERATIVE LENGTHENINGS



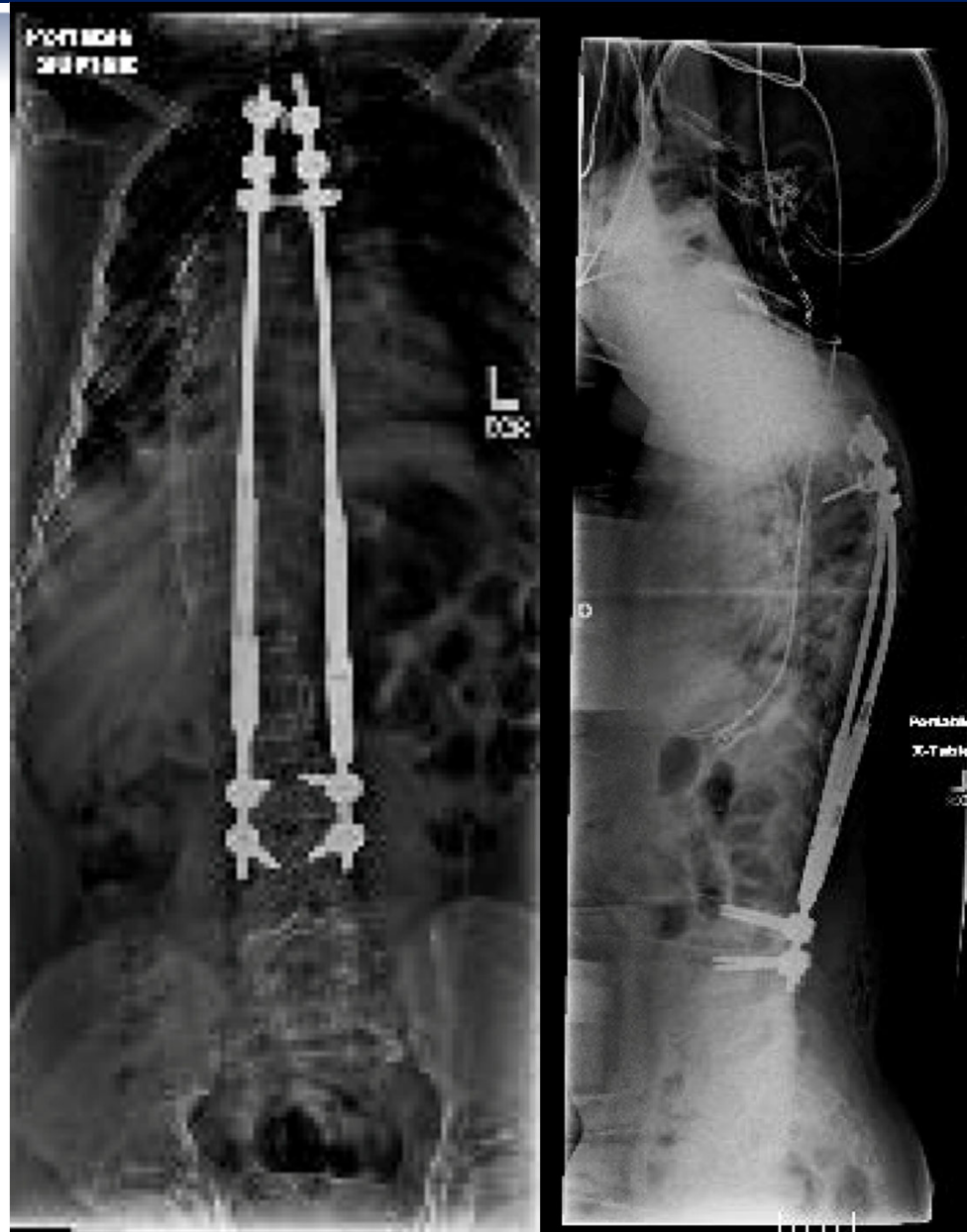
SEPT. 2014: US LENGTHENING WITHOUT PRE LENGTHENING XRAYs



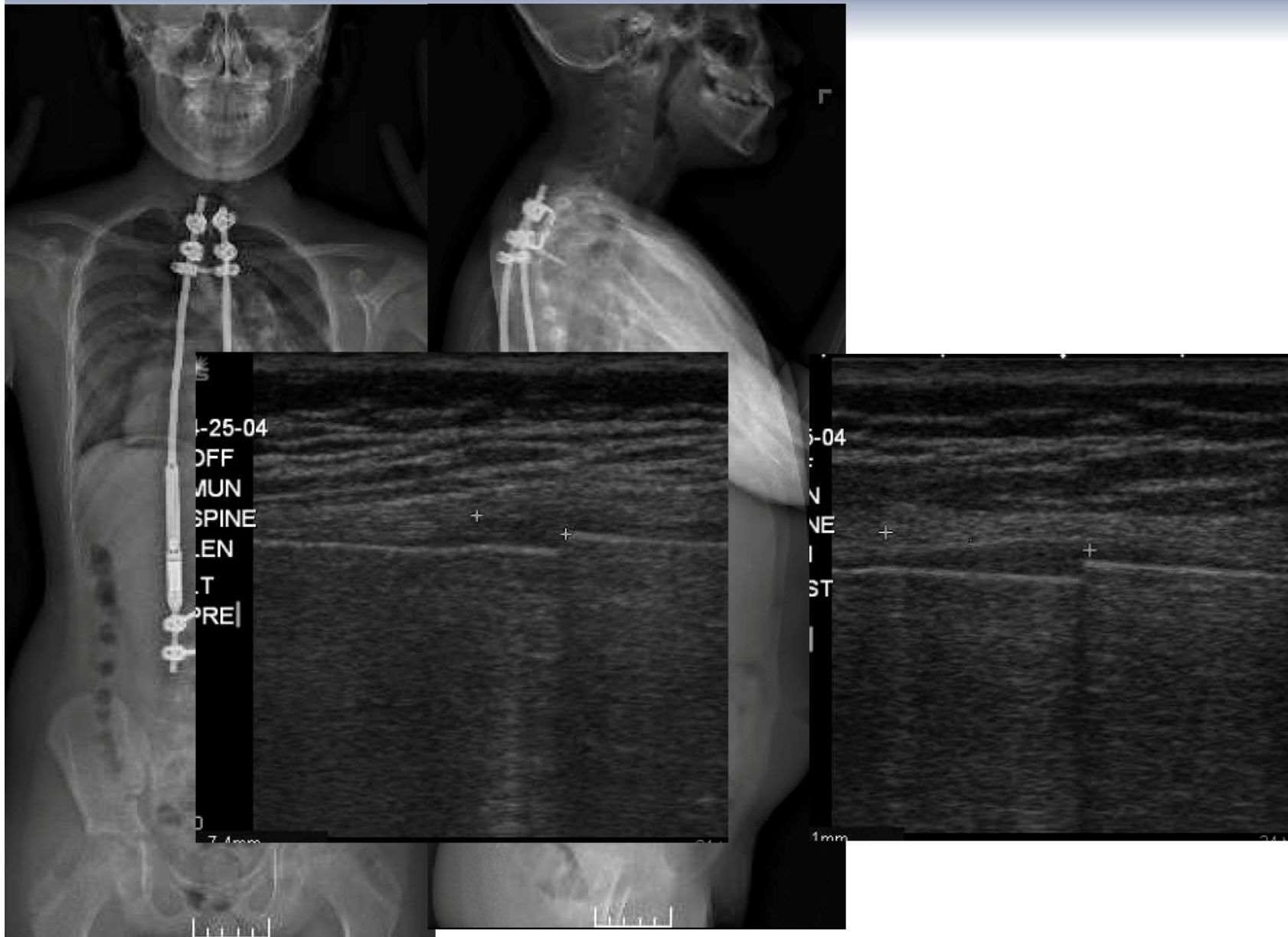
PAIN WITH LENGTHENING...POST US XRAYS



INTRA-OP REVISION



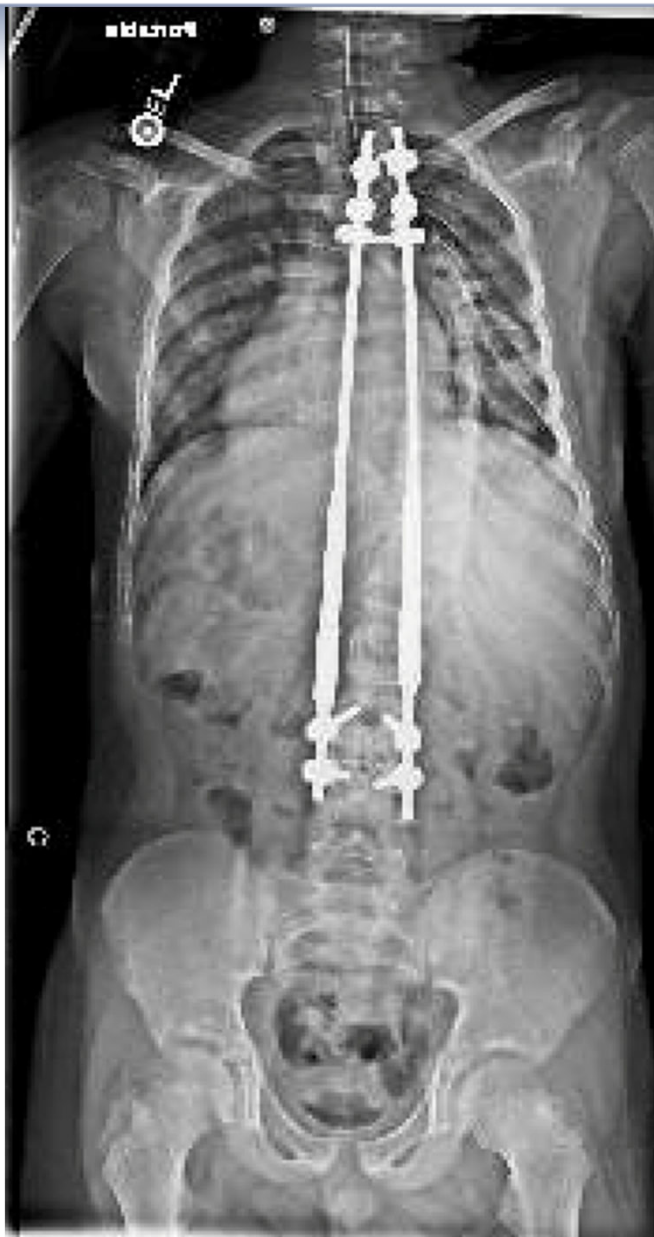
ROUTINE LENGTHENING X2



ONE MONTH LATER...NEW PAIN
AND A "POP" WHILE HIKING



REVISION #2, APRIL 2015



REVIEW

- ⊙ **Despite improved technology, the issues with rigid implants still exists**
- ⊙ **Unique issues:**
 - ⊙ Large curve: >60 after MCGR
 - ⊙ Large patient...complications happened at age 9 and 10
 - ⊙ Pt remains Risser 0 with open triradiate cartilage
 - ⊙ Still has significant growth remaining
 - ⊙ Cost of implants
 - ⊙ Has needed 3 total surgeries in 24 months...still better than 5?

IMPLANT- FINANCIAL

- ⊙ **What do we do when one rod breaks?**
- ⊙ **Traditionally: replace both rods**
- ⊙ **With MCGR???**
 - ⊙ Replace both?
 - ⊙ Tremendous cost burden for one...let alone 2

Provisional Recommendations:

- ⊙ The case for adopting the MAGEC system for spinal lengthening in children with scoliosis is supported by the evidence. Using the MAGEC system would **avoid repeated surgical procedures for growth rod lengthening**. This could reduce complications and have other physical and psychological benefits for affected children and their families.
- ⊙ Findings from cost modelling estimate that **using the MAGEC system is cost saving** compared with conventional growth rods from about **3 years** after the initial insertion procedure. The estimated cost saving per patient after 6 years is around £12,077 (~\$20,000 USD). The cost savings remained robust in sensitivity analyses.

Original article

Direct costs associated with the management of progressive early onset scoliosis: Estimations based on gold standard technique or with magnetically controlled growing rods



C. Charroin^a, K. Abelin-Genevois^b, V. Cunin^b, J. Berthiller^{c,d}, H. Constant^a, R. Kohler^b, G. Aulagner^{a,e}, H. Serrier^d, X. Armoiry^{e,f,*}

- ⊙ MCGRs are not reimbursed by insurance plans; their use is currently supported by hospital budgets.
- ⊙ **Results:** With a time horizon of **4 years**, the estimated direct costs of TGR and MCGR strategies were 49,067 D and 42,752 D, respectively leading to an incremental costs **of 6135 D in favor of MCGR strategy.**
- ⊙ The study emphasizes that conventional strategy using TGR leads to substantial costs for the French sickness fund even though the overall economic burden is rather limited considering the rarity of EOS cases treated surgically.

PATIENT SPECIFIC FACTORS

- ◎ **PATIENT RELATED**
 - ◎ Severe kyphosis



PATIENT SPECIFIC FACTORS

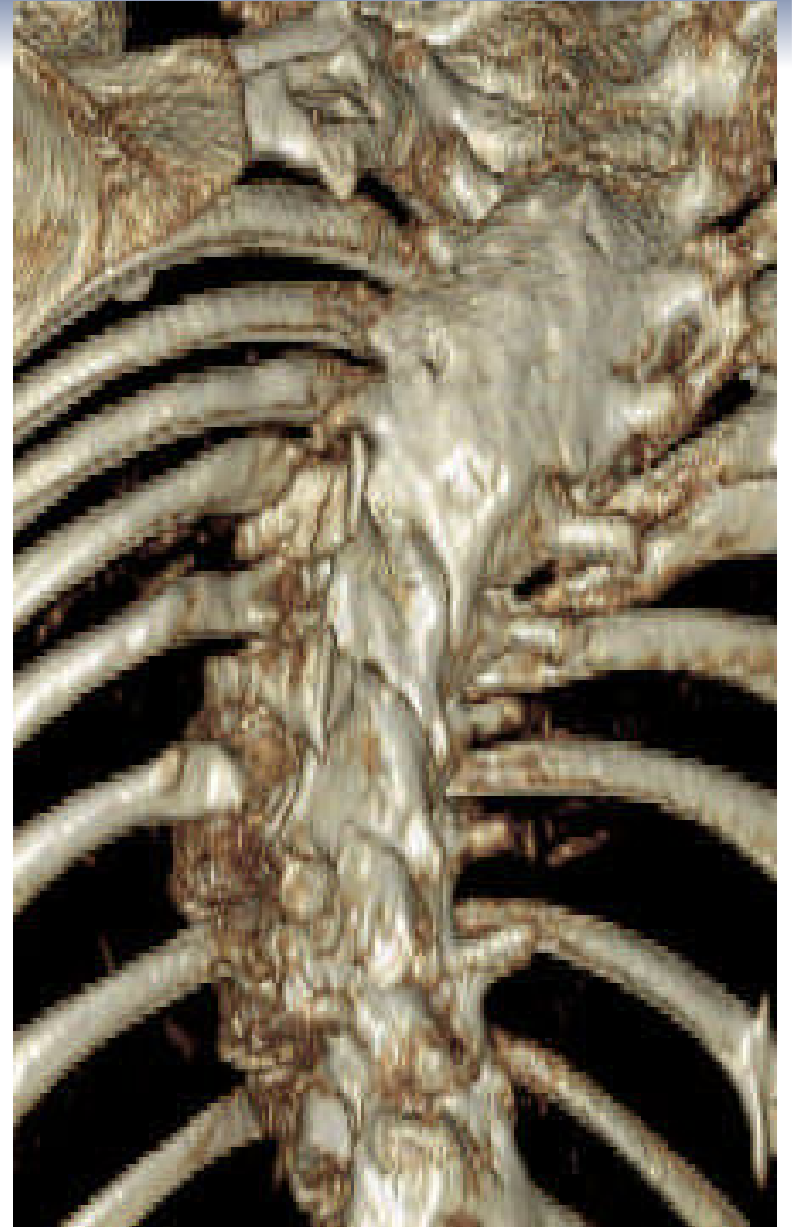
⊙ PATIENT RELATED

- ⊙ Severe kyphosis
- ⊙ Large curves?



PATIENT SPECIFIC FACTORS

- ③ **PATIENT RELATED**
 - ③ Severe kyphosis
 - ③ Large curves?
 - ③ Stiff curves?

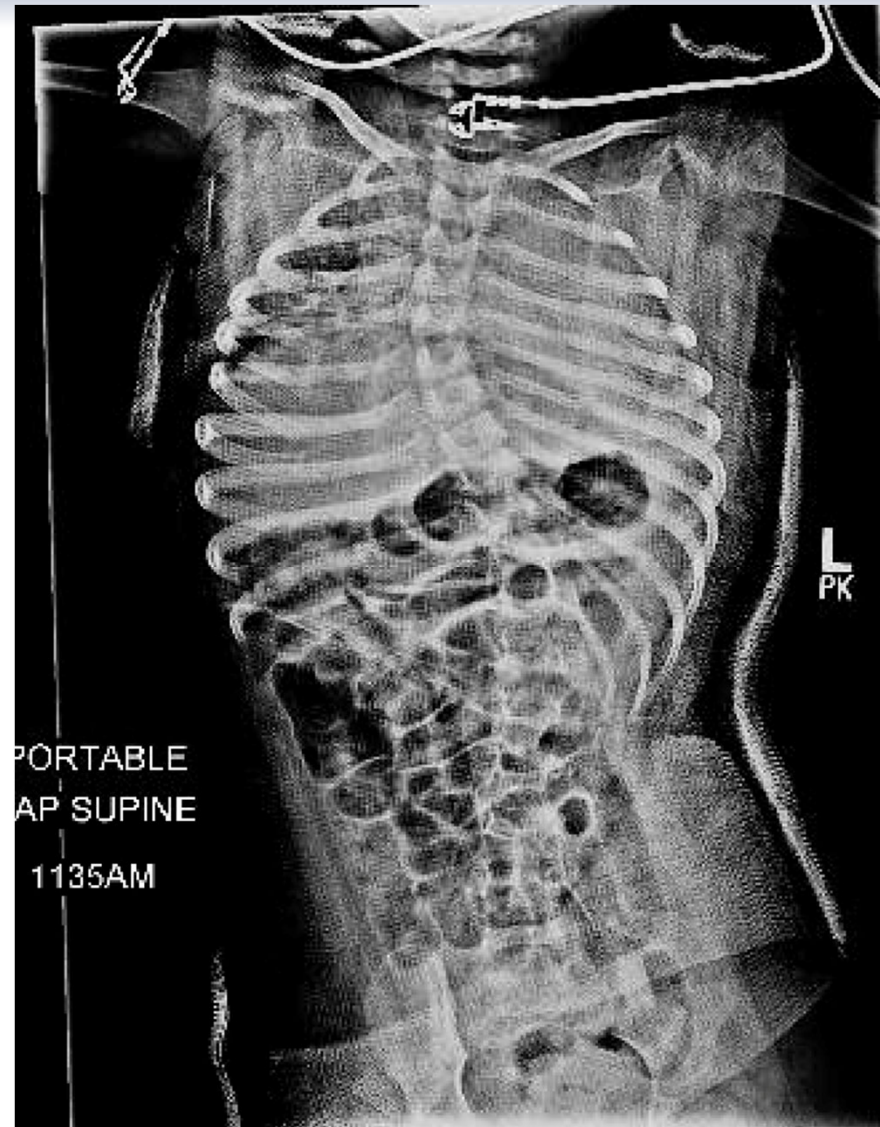


PATIENT SPECIFIC FACTORS

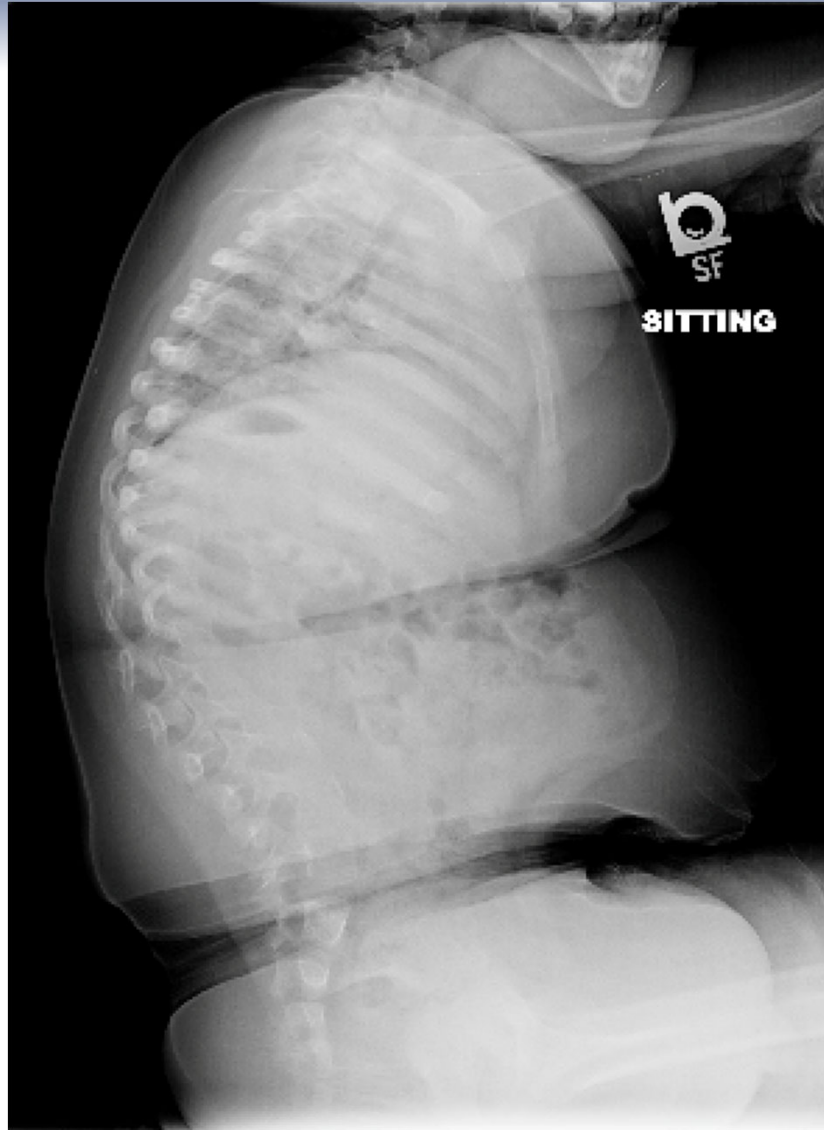
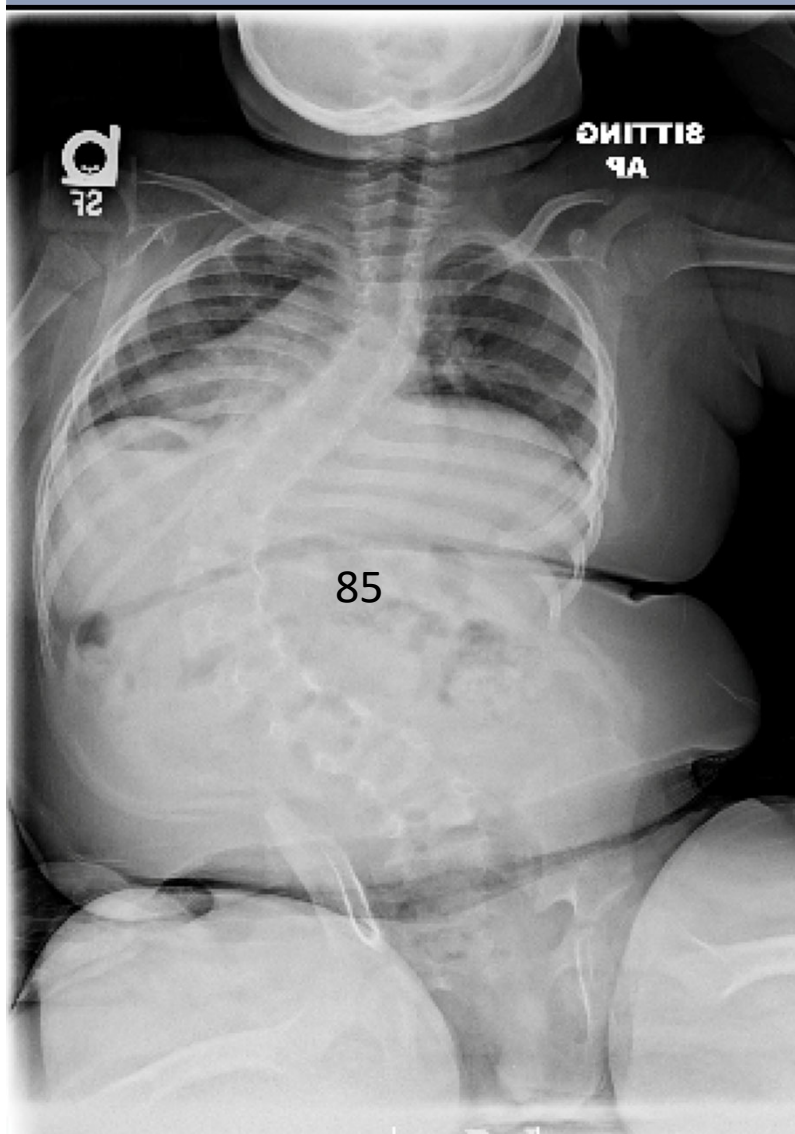
⊙ PATIENT RELATED

- ⊙ Severe kyphosis
- ⊙ Large curves?
- ⊙ Stiff curves?
- ⊙ Conversion
patients

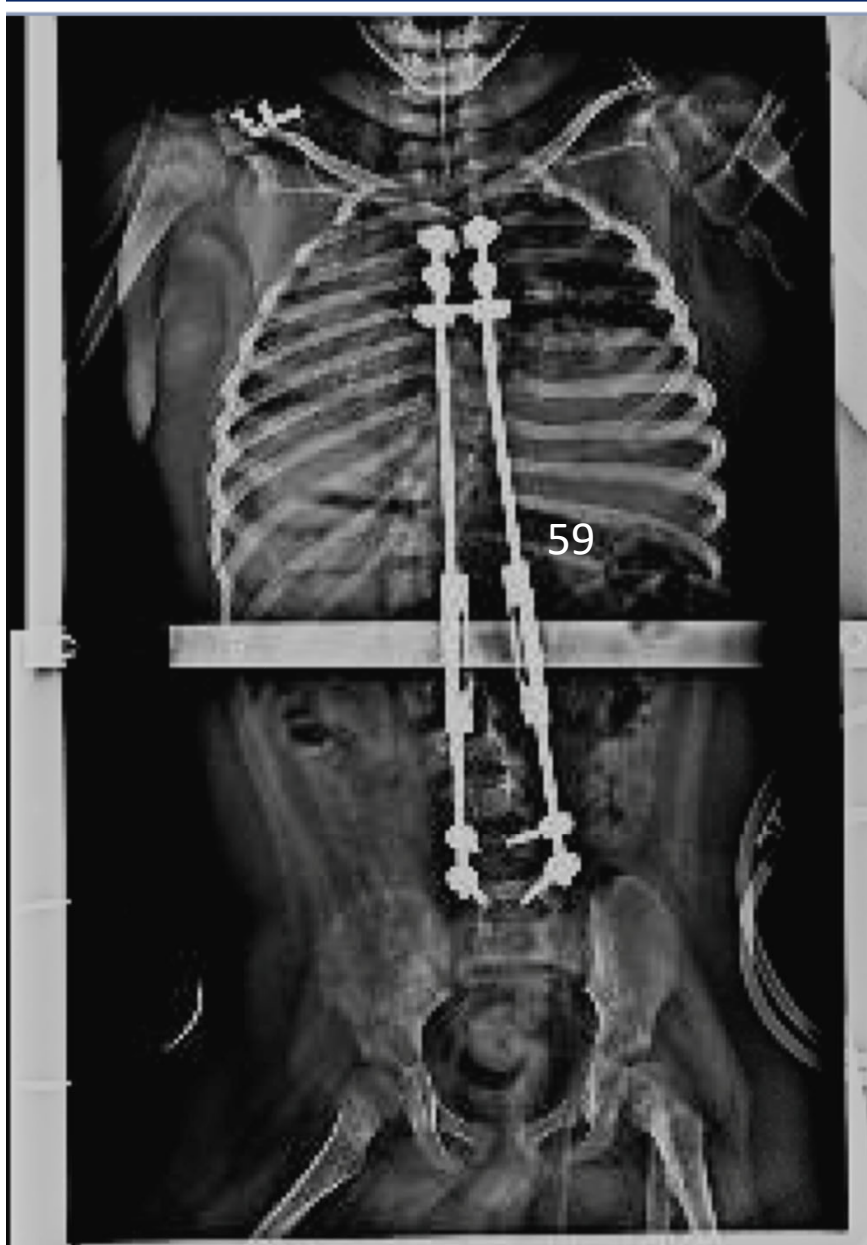
CASE 1: CASTING AT 3-4 YEARS OF AGE



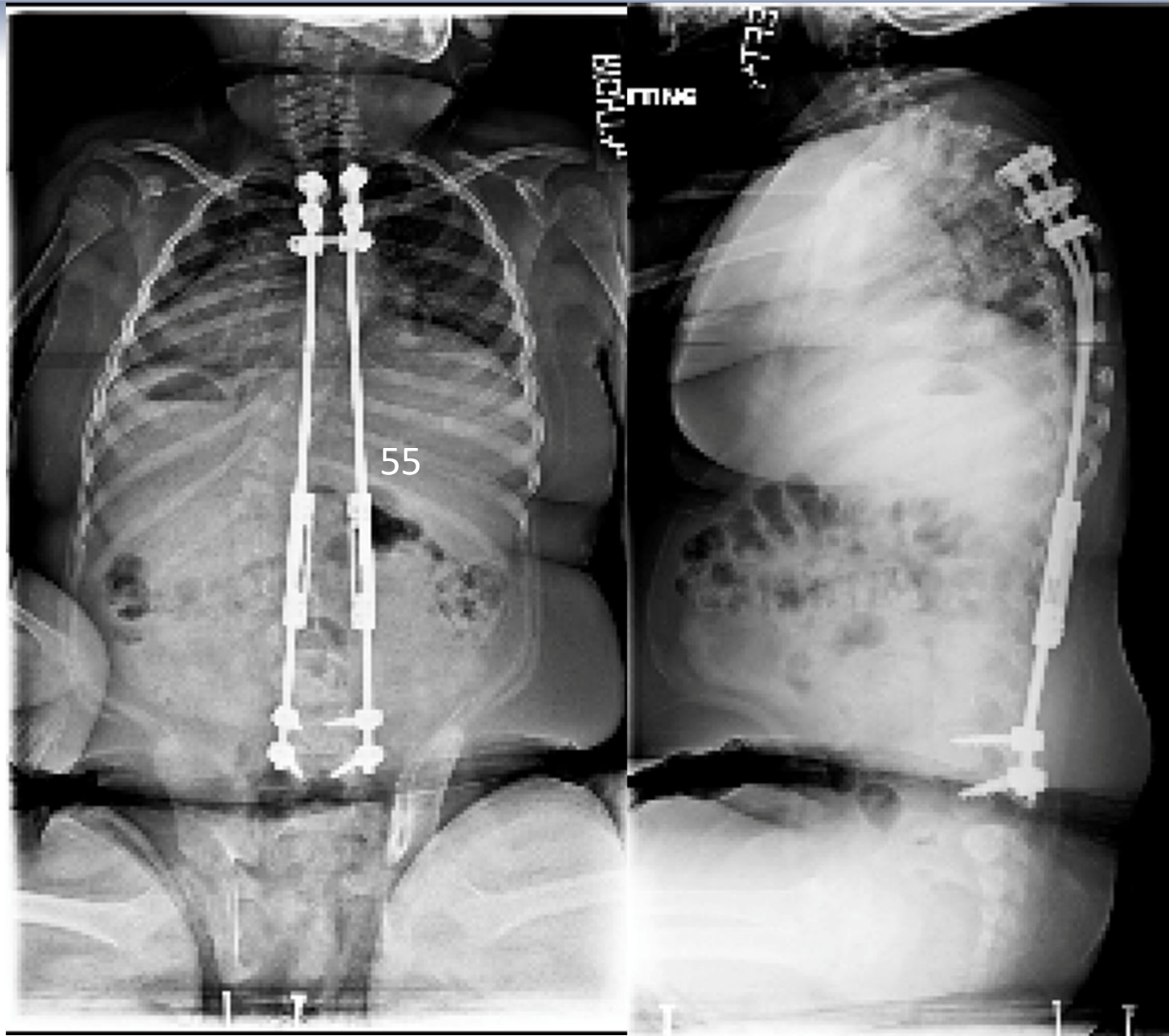
CASE 1: 4 YO WITH PWS



8/16/2011 AGE 4

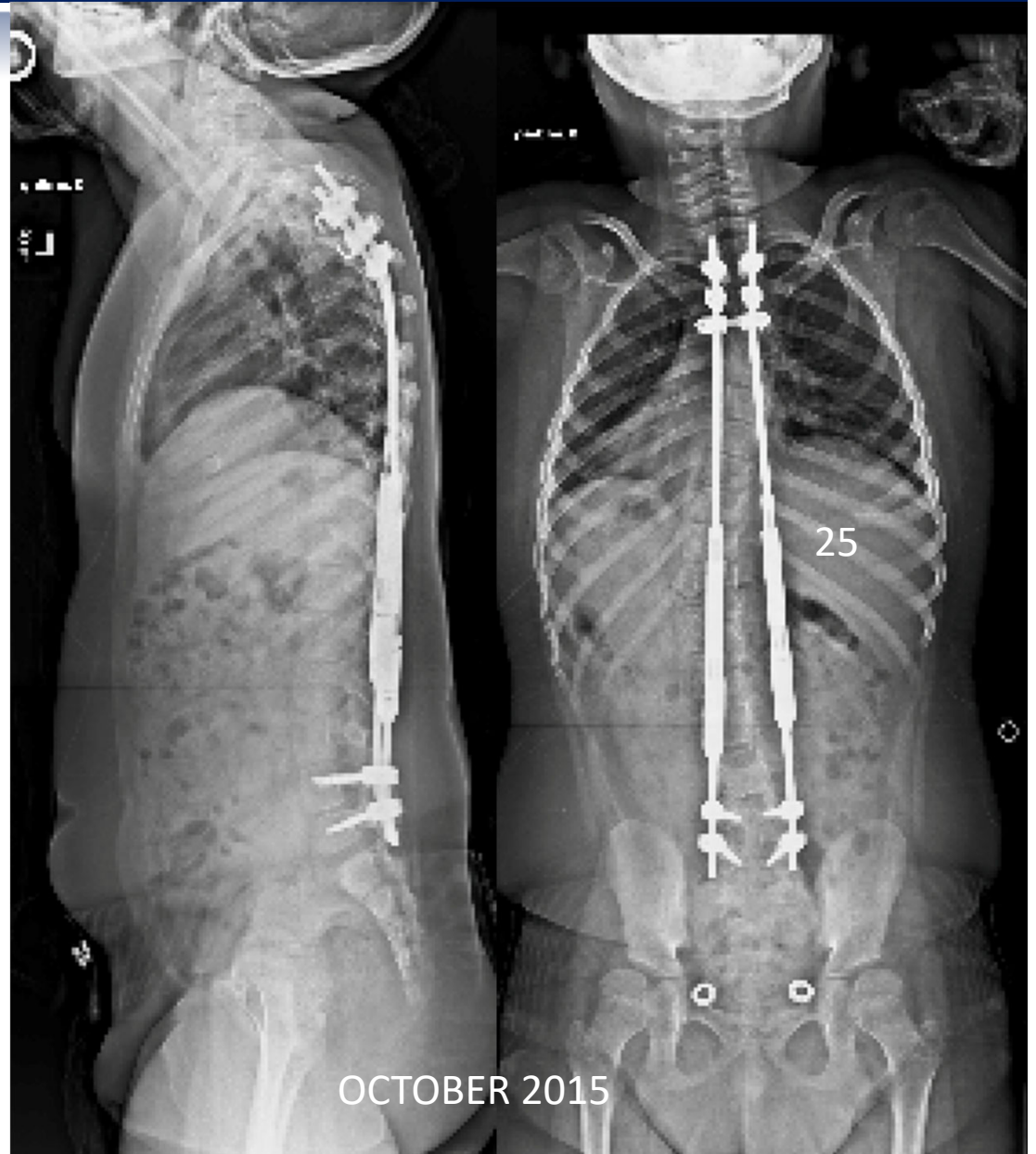


TGR AFTER 2 YEARS OF LENGTHENING

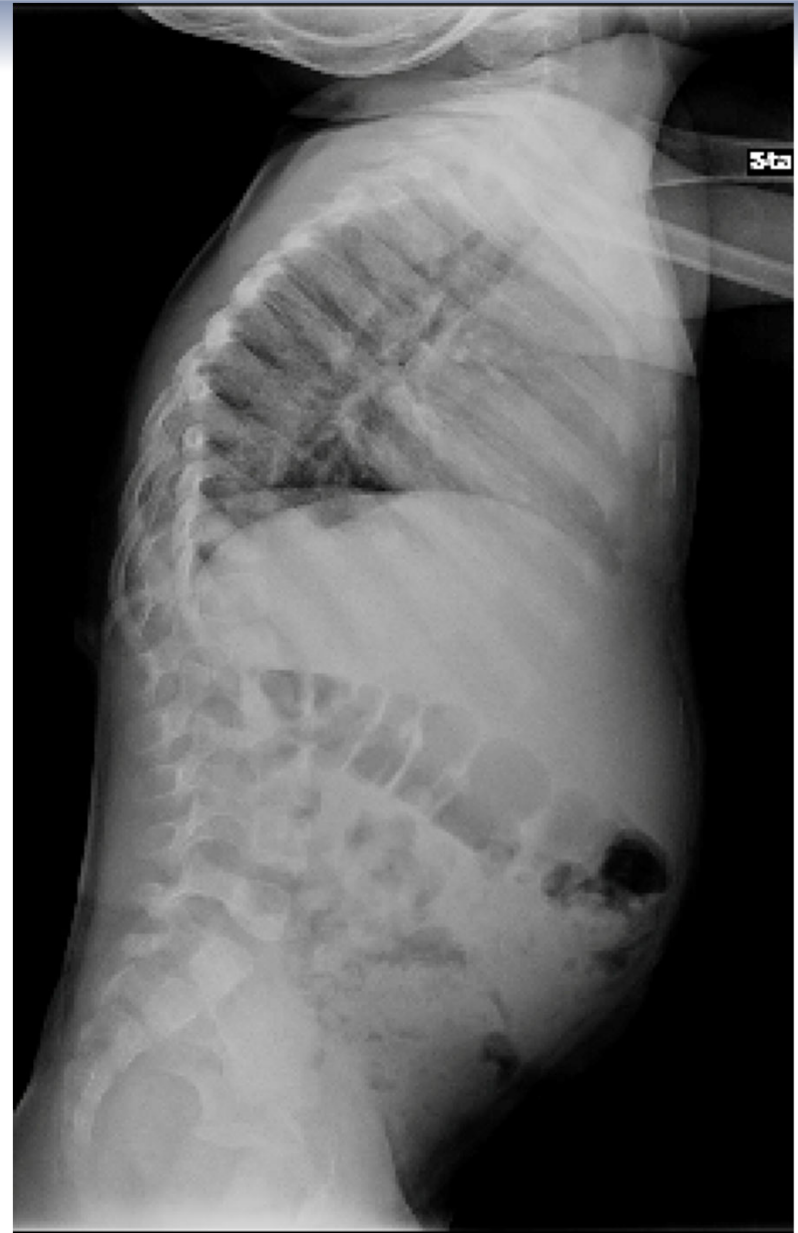
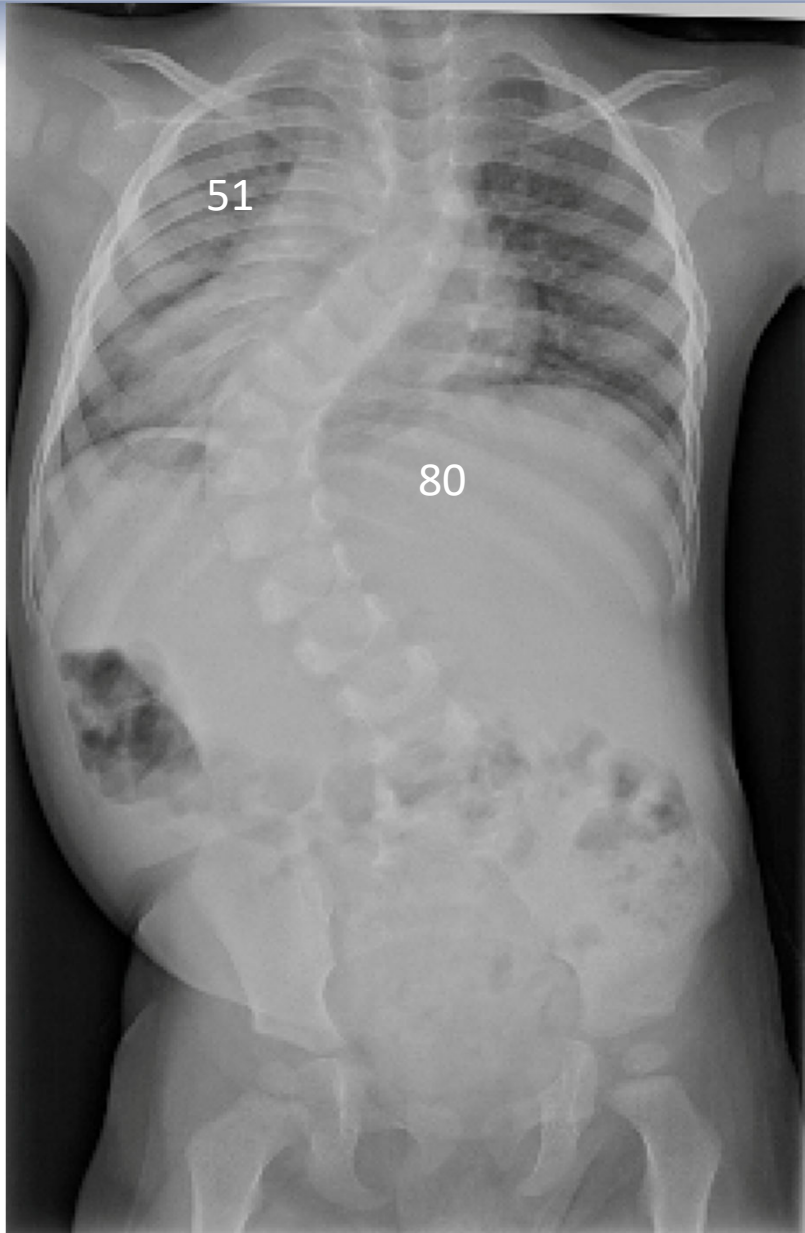


2014 AGE 7 CONVERSION TO MCGR NOW WITH 4 DISTRACTIONS

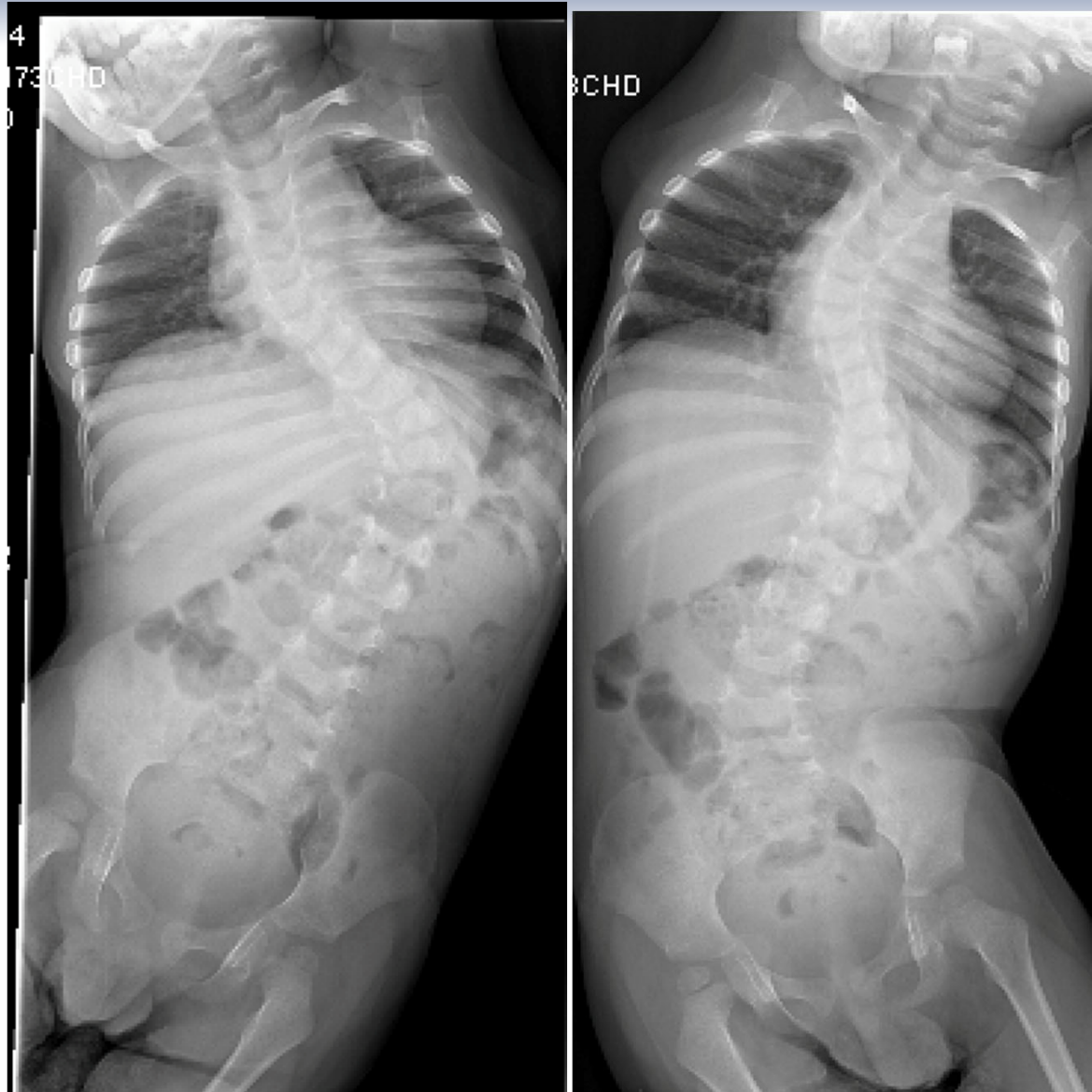
SUCCESS?



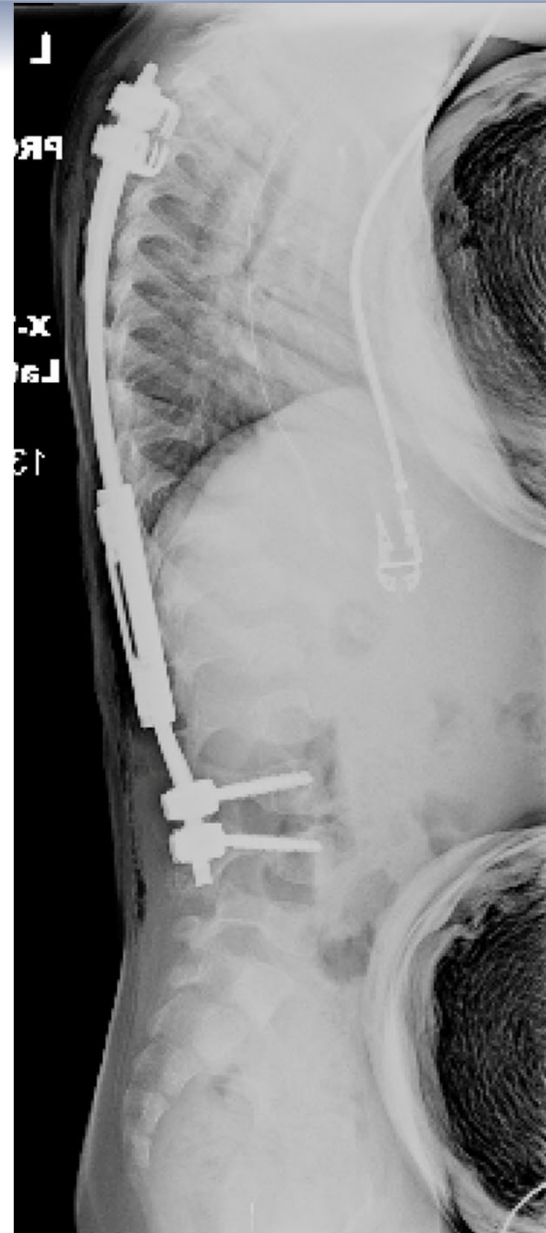
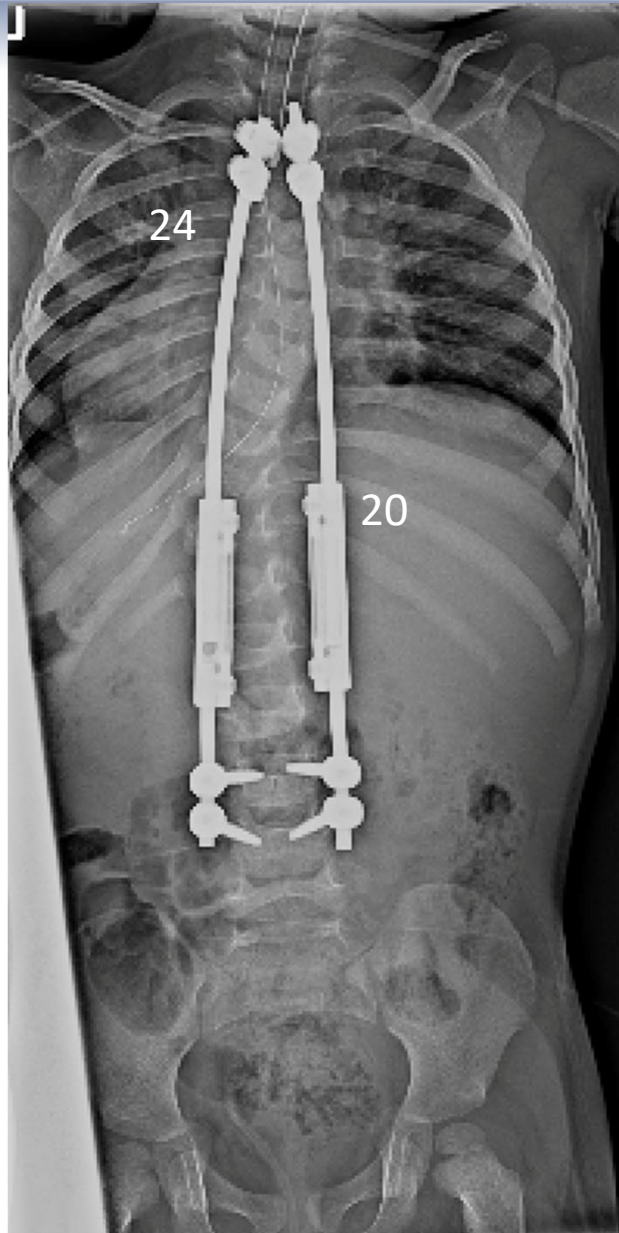
CASE 2: 2 YEAR OLD BOY WITH PWS



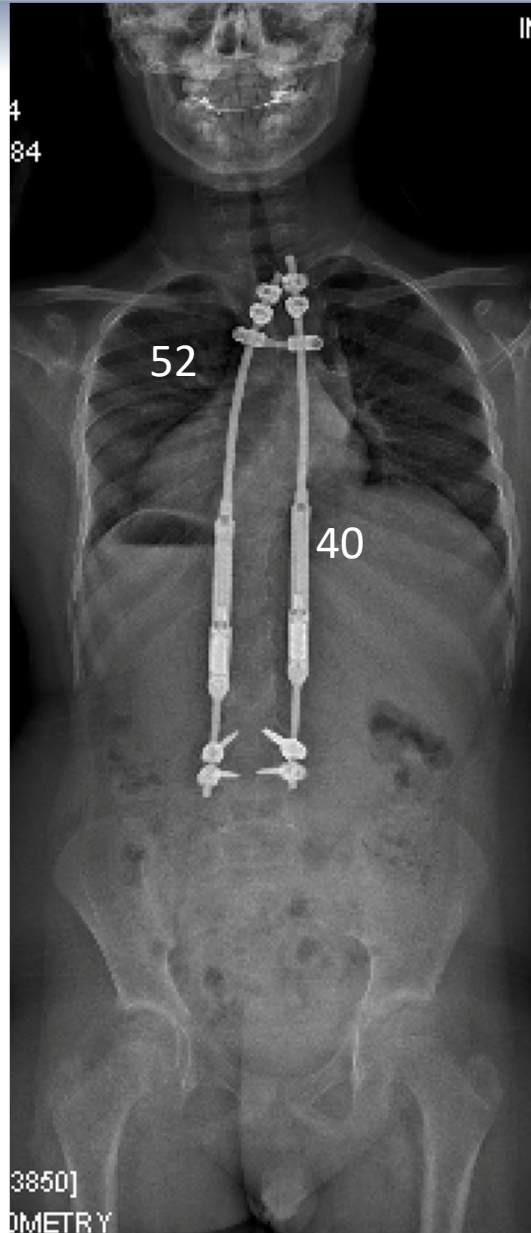
CASE 2: 2 YEAR OLD BOY WITH PWS



AT 3 YEARS OF AGE- TGR



2014 CONVERSION TO MCGR AT AGE 8



NOVEMBER 2015- 9 YO

- ⊙ Last 3 distractions have max'd out at 1 mm bilateral



COMPARISON OF PRIMARY VS. CONVERSION SURGERY WITH MCGR RODS IN CHILDREN WITH EOS

- ⊙ 27 Primary (mean age 7.0 ± 2.2 years at surgery)
- ⊙ 23 C patients (mean age 7.7 ± 2.4 years)
- ⊙ P underwent mean 8.0 ± 5.5 and C 3.5 ± 2.4 lengthenings at last follow-up ($p=0.0006$)
- ⊙ 22 patients having a minimum 2-yr FU (mean FU time 22.4 ± 7.9 months for P and 17.3 ± 5.9 for C, $p<0.05$)

CONCLUSIONS

- © **Satisfactory** correction can be achieved with **primary** MCGR and **maintained** following **conversion** to MCGR
- © **Spinal growth** with subsequent non invasive lengthenings is **less in conversion** patients compared to **primary**

SOCIAL- INSURANCE ISSUES

- ◎ **SOCIAL**
 - ◎ Insurance issues
 - ◎ Presently not a huge issue
- ◎ **Cost data may make this a bigger issue**
- ◎ **It is an issue internationally as many novel devices are too expensive to be used in non-US countries**



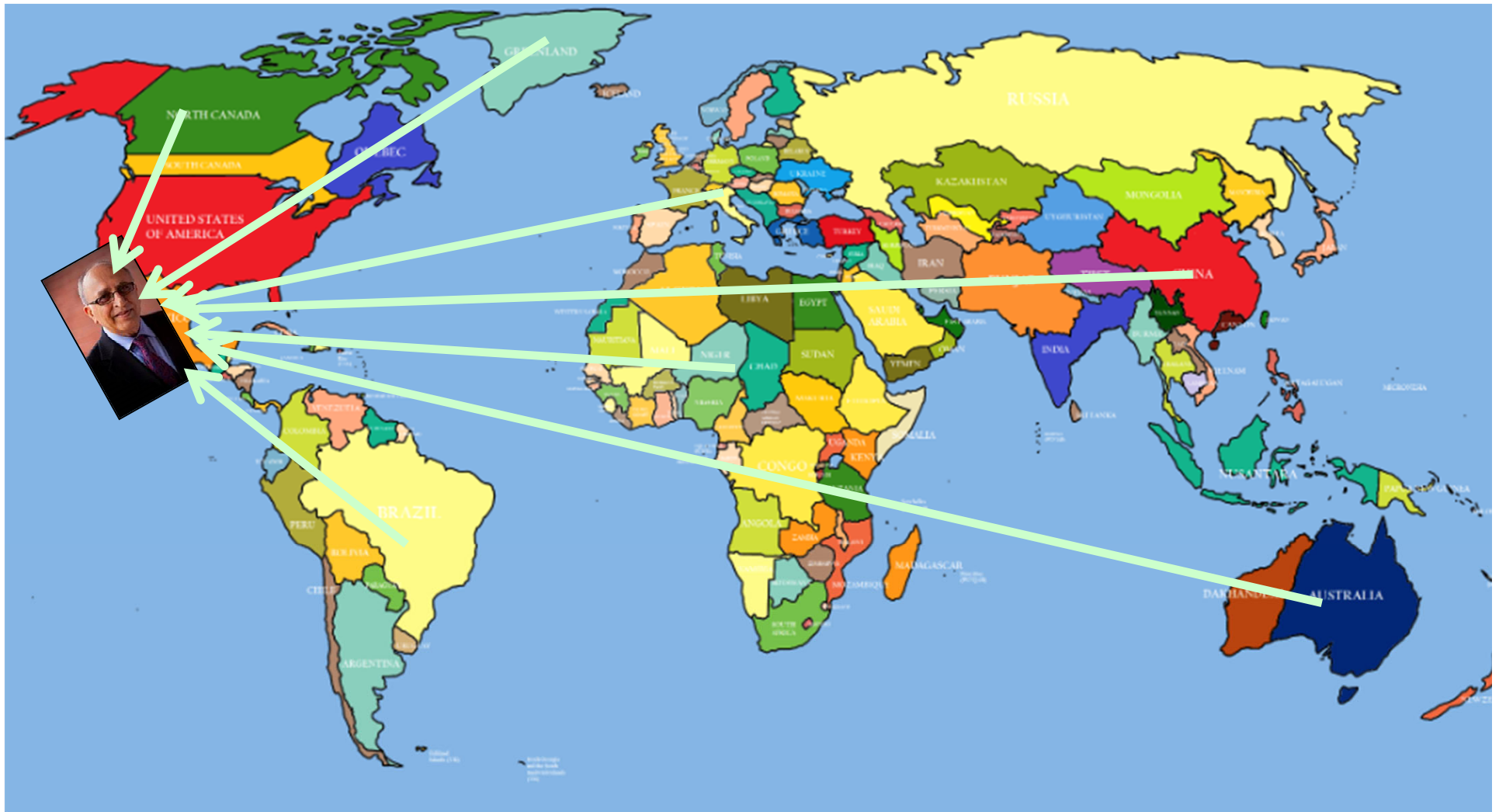
"Looks like your medical insurance does not cover pre-existing organs."

SOCIAL- HOSPITAL ISSUES

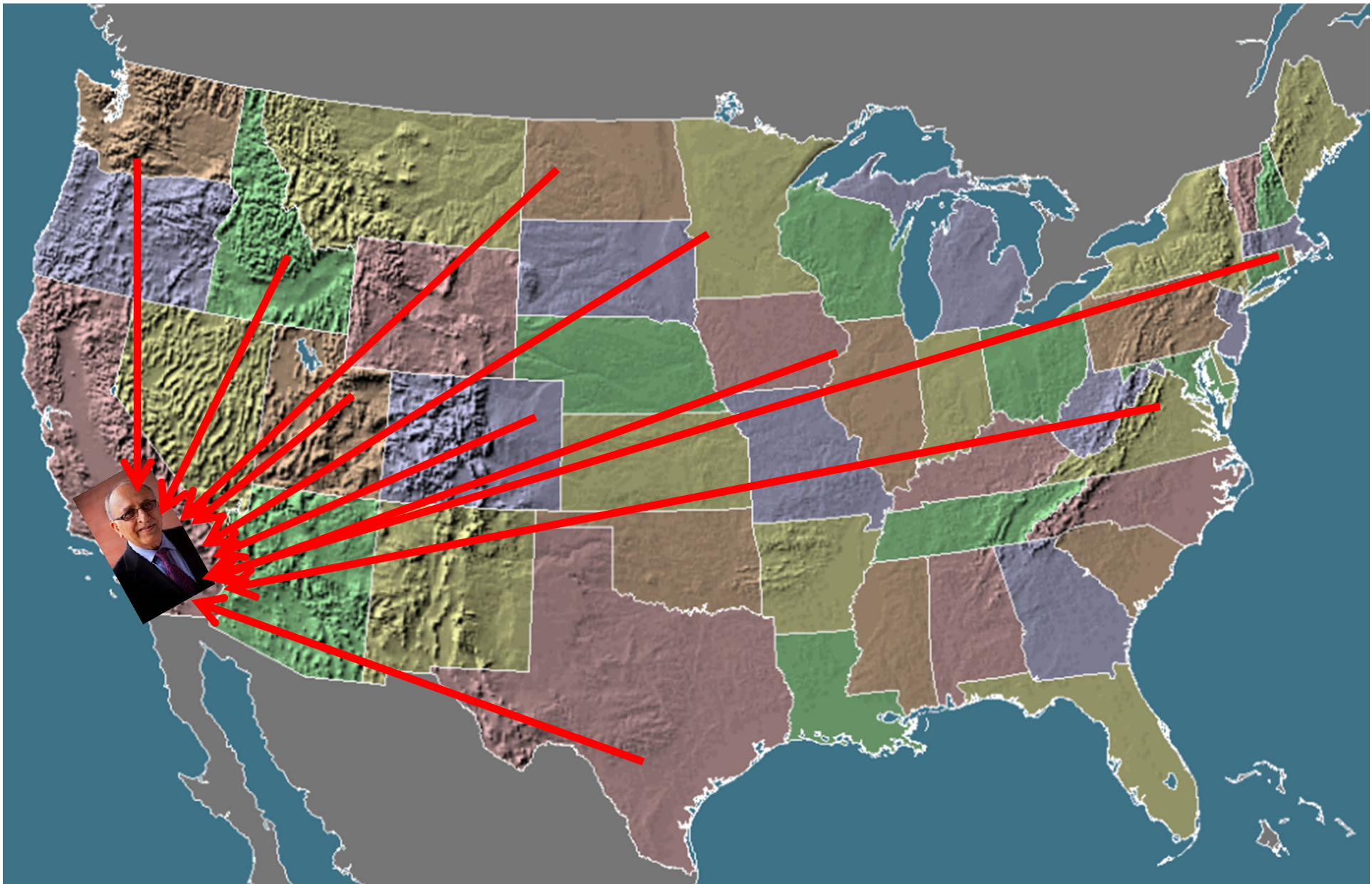
- ◎ **There is a disincentive**
 - ◎ Lengthening surgery is great
 - ◎ Short
 - ◎ Frequently outpatient
 - ◎ Has relatively high DRG value for reimbursement
- ◎ **Who covers the cost of the implant if insurance denies it or only partially reimburses**



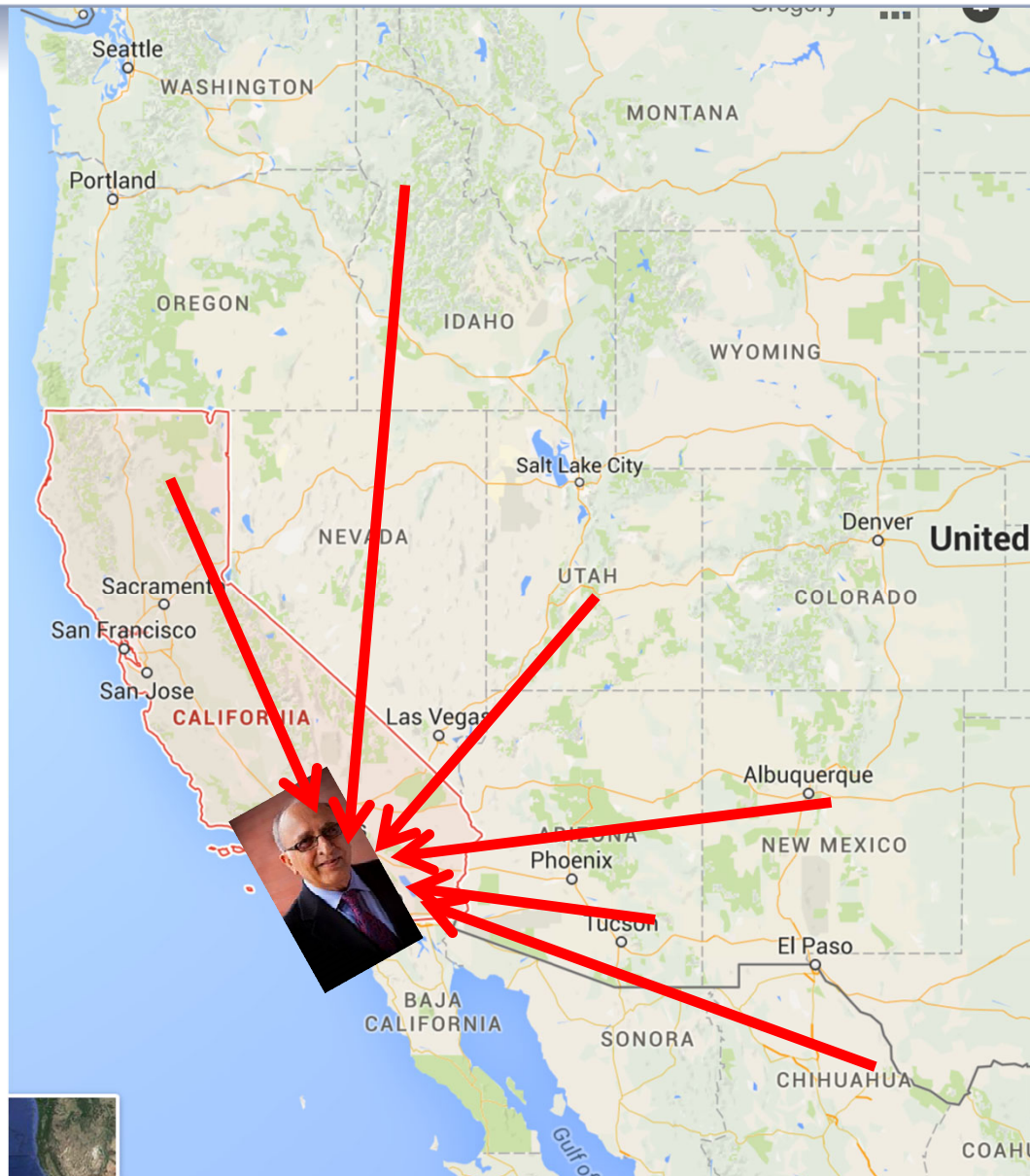
SOCIAL- TRAVEL FOR FAMILIES



SOCIAL- PATIENT TRAVEL



SOCIAL- REGIONAL TRAVEL



Early Onset Scoliosis Team- San Diego

THANKS

**Rady Children's Hospital
EOS Program 2015**

