Phenix Spine Rod and Childhood Scoliosis

The Early Results

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Disclosures

- Consultant to Medtronic Spine
- Designer of Variable Axis Connector
  - No Royalties
- Phenix and Medtronic have no connection

Early Onset Severe Scoliosis

- - unsolved problem in spinal deformity surgery

The Cure is the “Holy Grail” of orthopaedic surgery

In this quest there will be disappointments……

……. and challenges

- There will be a few cheap imitations…….

Surgery

- Non-fusion or “Growth Rods” have been used for 40 years.
- Failure rates were (are) high
- Reoperating every 6 months is depressing, and time consuming for both patient and surgeon.


MONTY PYTHON
AND THE HOLY GRAIL
Written and performed by
GRAHAM CHAPMAN
JOHN CLEESE
TERRY GILLIAM
ERIC IDLE
TERRY JONES
MICHAEL PALIN
with
CAROL CLEVELAND
CONNIE BOOTH
JOHN YOUNG
DVD VIDEO
PG
PARENTAL GUIDANCE RECOMMENDED
FOR PERSONS UNDER 15 YEARS

Dual Rod Systems

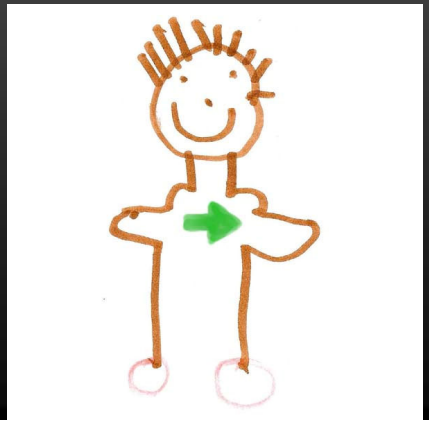
- Certainly better than single devices for hook loss
- Less complications but still > 30%
- Still need repeated operations for years
- Spontaneous fusion still occurs

Phenix Rod

- Arisen from a desire for a lengthening device, with internal power and avoiding repeated operations.

The Phenix Philosophy

- Aims:
  - To correct deformity
  - Avoid repeated operations
  - Constant correction - allow growth to modify deformities
  - Instrument only the primary curve i.e. avoid top to bottom instrumentations
  - Parent lengthening – ie ownership



…….child of these two Frenchman

Jean Dubousset

Arnaud Soubeiran

Superb intellect plus talented orthopod and engineer

Phenix System

- Based on magnetised internal system with an external control magnet.
- i.e. by manipulating a magnet close to the device the internal driver can be controlled to lengthen or shorten.

Demands of any Growth System

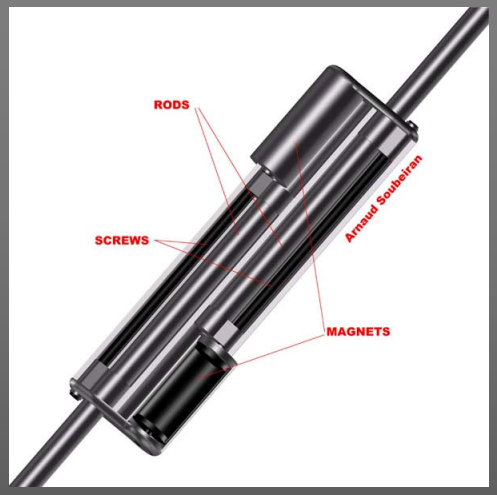
- Horsepower – in this case the Phenix Rod
- Fixation to the Spine
  - Hooks and screws
  - Fixation between the driving rod and the hook/screw complex.

Phenix Rod System

- **Spine Rod** - 3 versions to date
  - Version 1
    - used a reciprocating action of the drive magnet
    - 5cm capacity
    - One way device
    - Required about 50+ Magnet movements per mm.

- 3 versions of the spinal rod
  - Version 2
    - 1 motorised rod,
    - revolving action of driving magnet
    - two way device
    - 5cm capacity
    - Only 5 revolutions per mm.

- 3 versions of the spinal rod
  - Version 3
    - Two driven rods
    - 5 rev's per mm each rod
    - Two way device
    - Each rod can deliver 4+ cm.
      - Total capacity depends on design
    - Cylindrical driving magnet
  - To date more reliable, efficient, more user friendly.



The Phenix Family…….

Malmo
Sweden

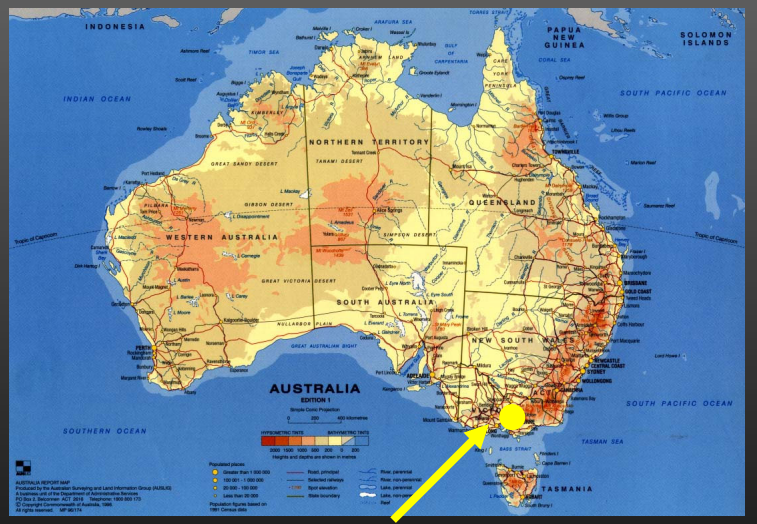
Zurich
Switzerland

Paris

Montpellier
France

Grenoble
France

Portland
Oregon



Melbourne
Australia

The Australian Series to date…….

Patient Profile (13)

- Syrinx 2
- Spina Bifida 1
- Cong Rib Fusions/Cong Scoli 2
- Cong Heart Disease 2
- Neurofibromatosis 1
- Fibromatosis 1
- Syndromic 1
- Myopathy 1
- Autistic 1
- Marfans 1

Note: No true idiopathic patients

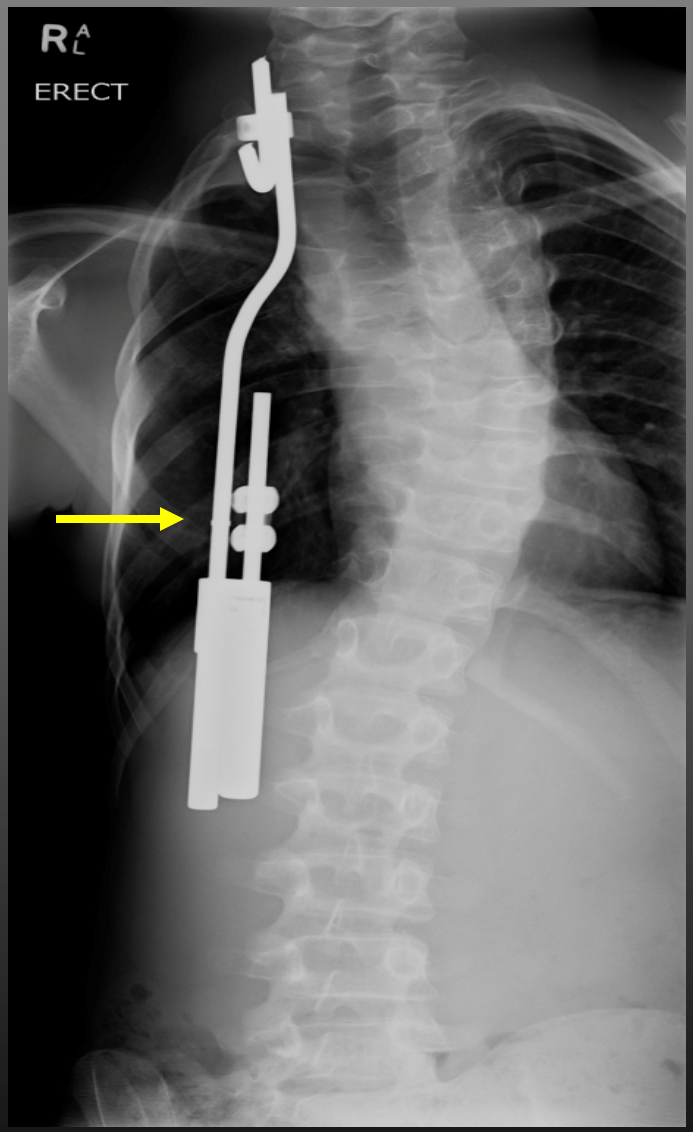
SUPINE

PRONE

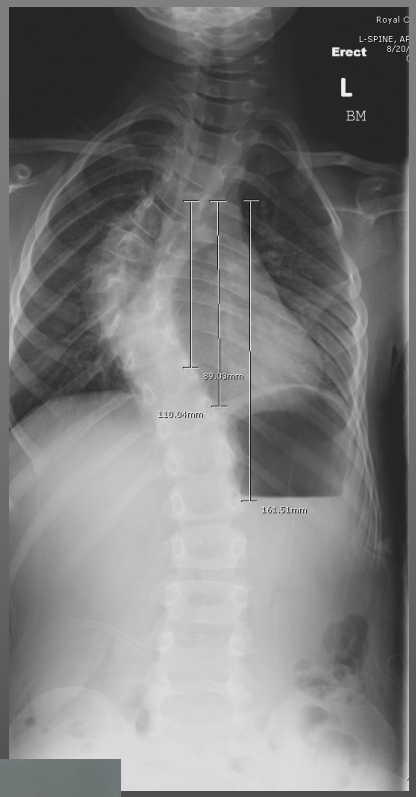
PRONE

Abandoned

Magnetic Growth Rod as “VEPTR”

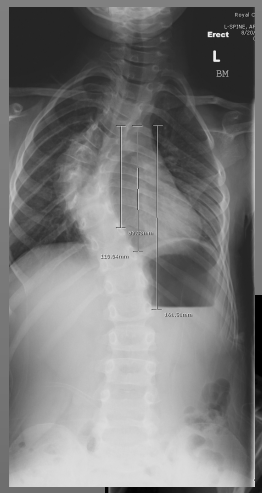


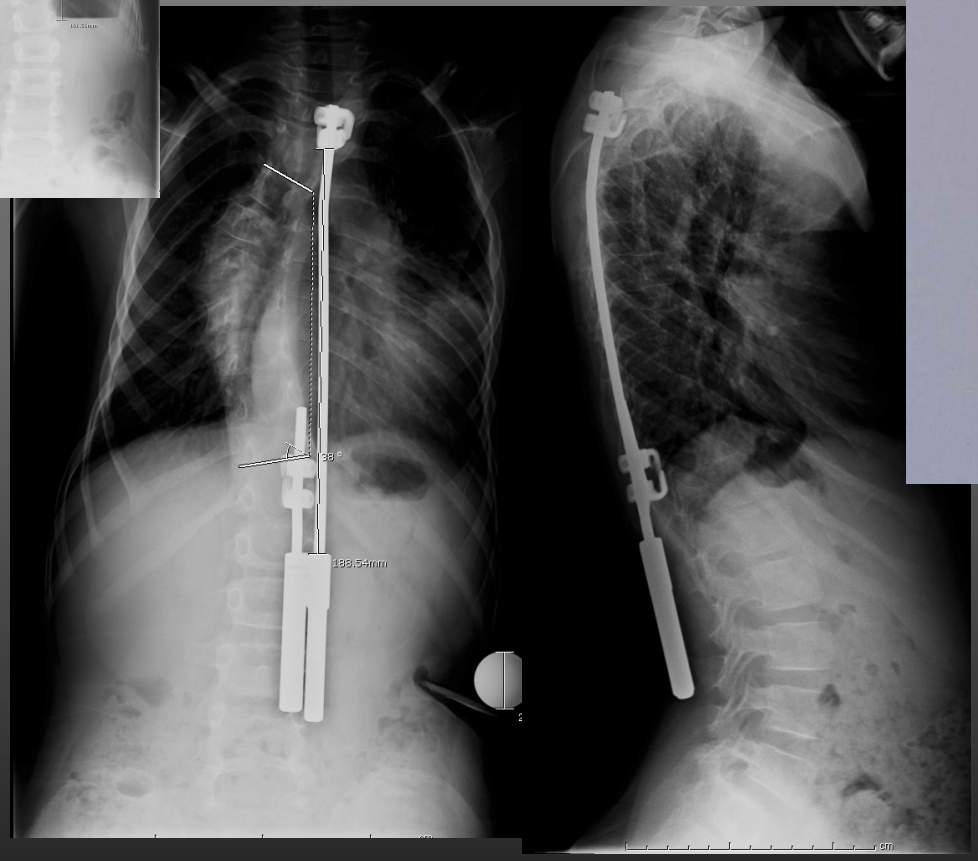
Tibial Hemi

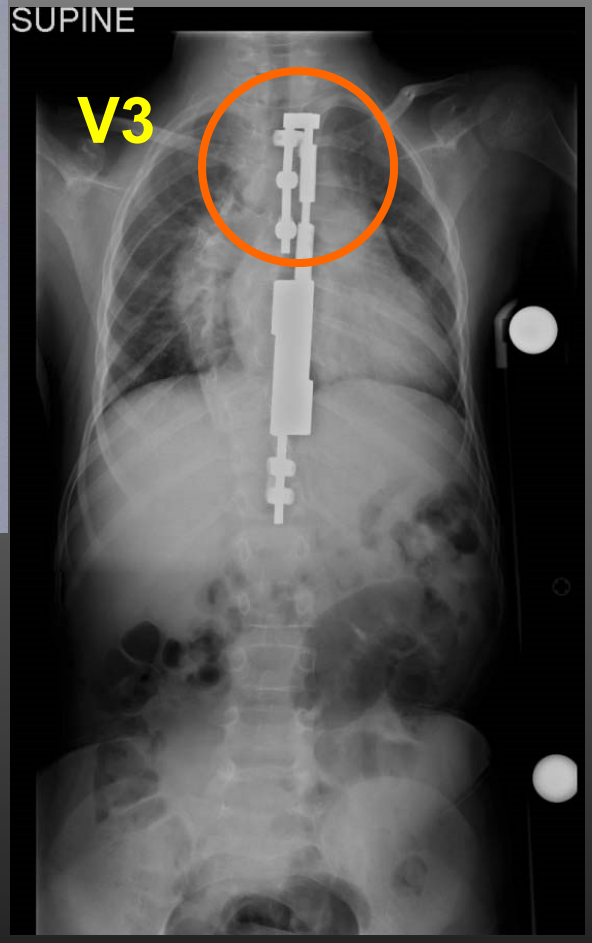


7yrs NF1

MF





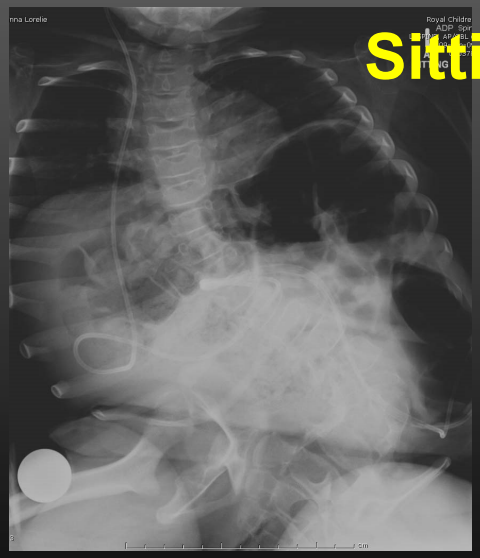


45mm in 8m.

Total length to date = 54mm

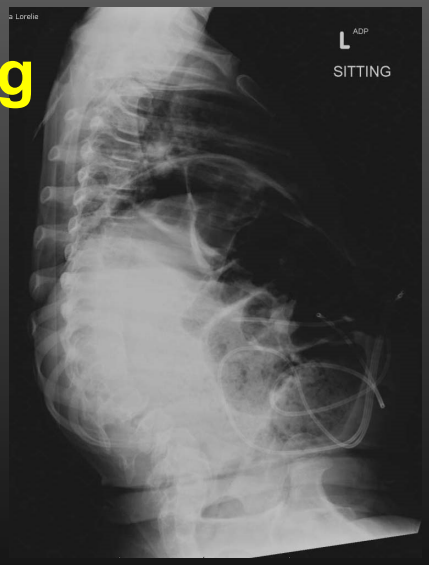
MF

Spina Bifida

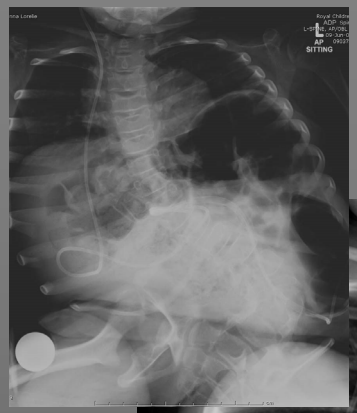


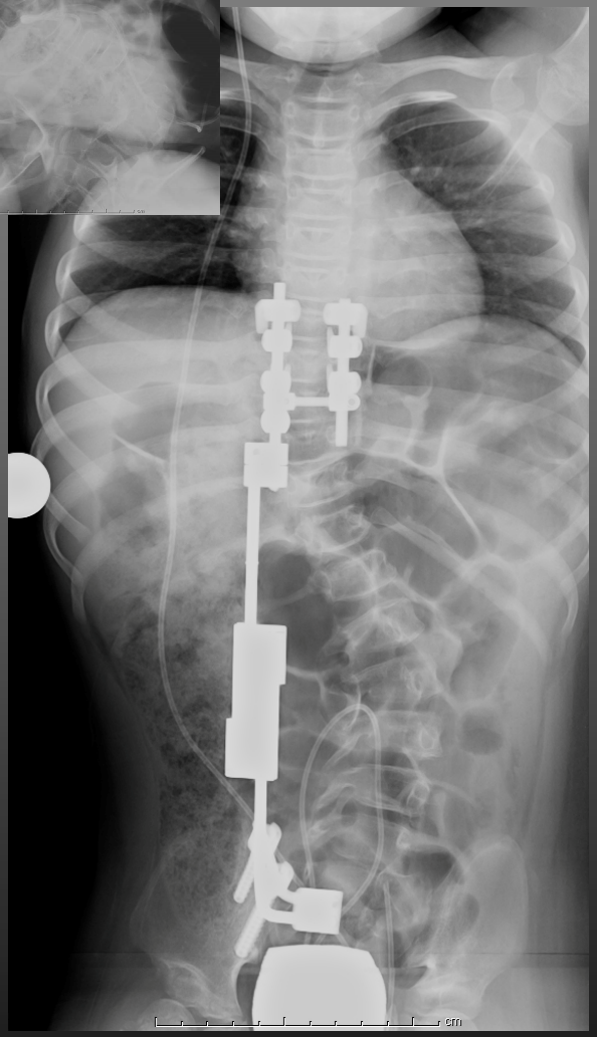
HH

Sitting

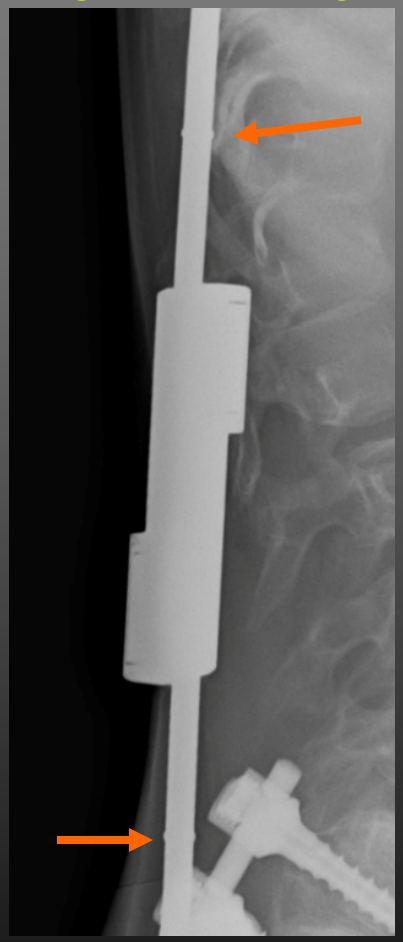


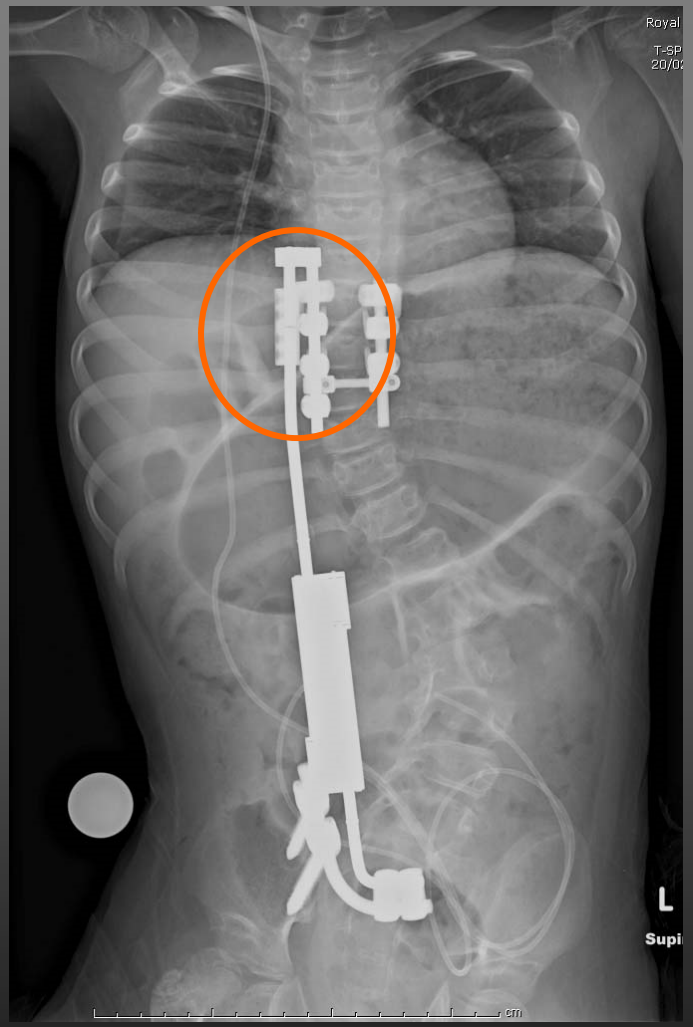
Supine stretch



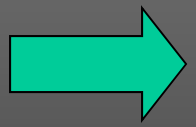


45 mm in 6m





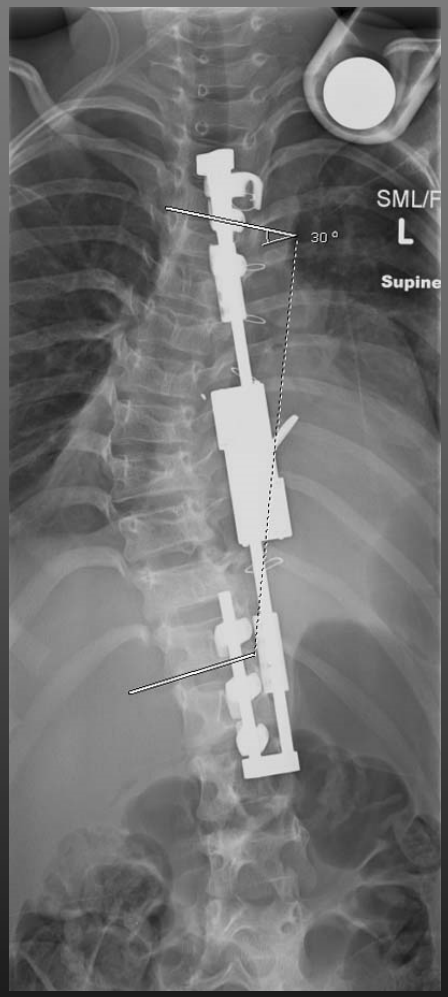
Total Gain to Date 90mm



M.B. 7yrs Marfans
Cardiac involvement – valve replacement


PA
ERECT
60 °


R
Erect


30 °
L
Supine


R
SML/FR
Horizontal
Beam

Fixation between the Phenix rod and the Spine

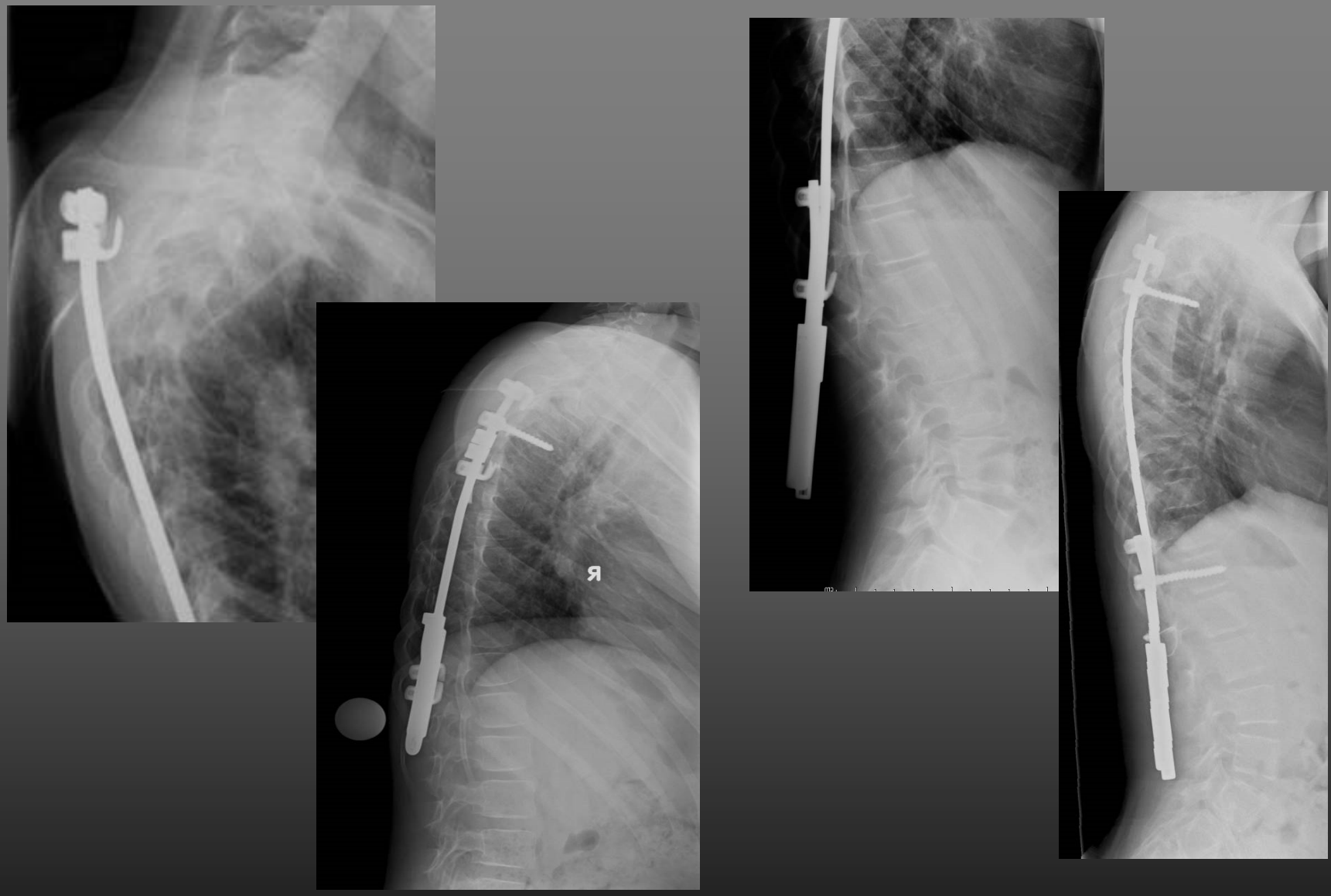
- Fixation to the Spine
  - Choice of hooks or screws
- Connection between rod and hook construct
  - Solid vs. flexible

Modes of Failure

- 1. Fail at fixation to spine
  - Hook or screw loss of fixation
- 2. Failure of connection to Phenix rod
  - Fuse technique
- 3. Failure of Phenix Rod

Hooks vs Screws

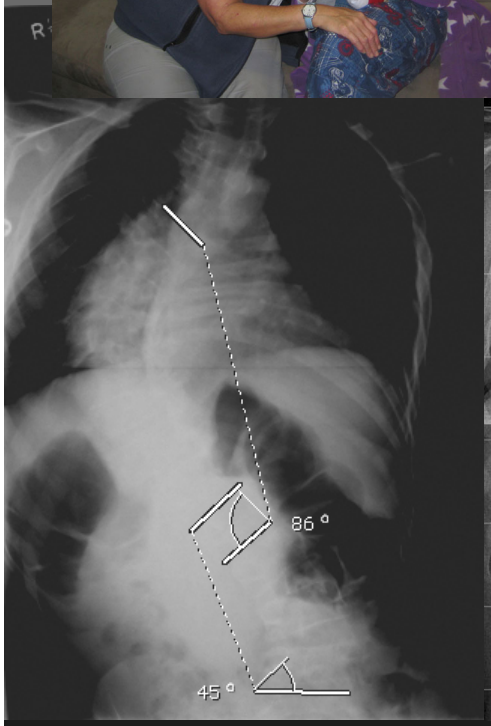
- Most of these cases have hook fixation
- Why?
  - Bias from 30 years frustrations
  - Need a second option
    - When hooks fail – fall back is screw
  - Screw failure potentially devastating

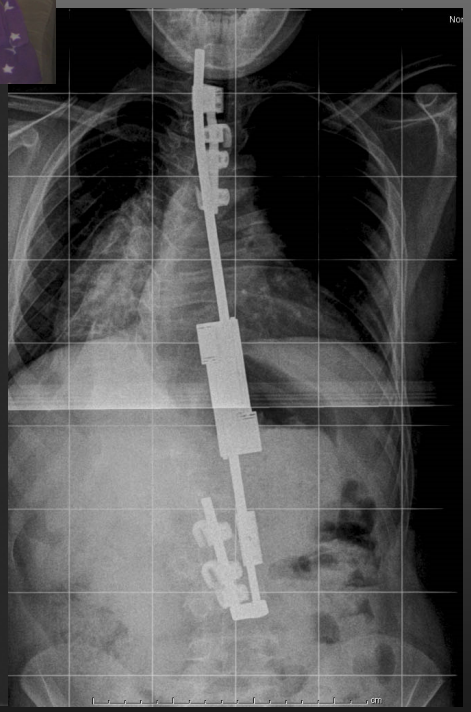


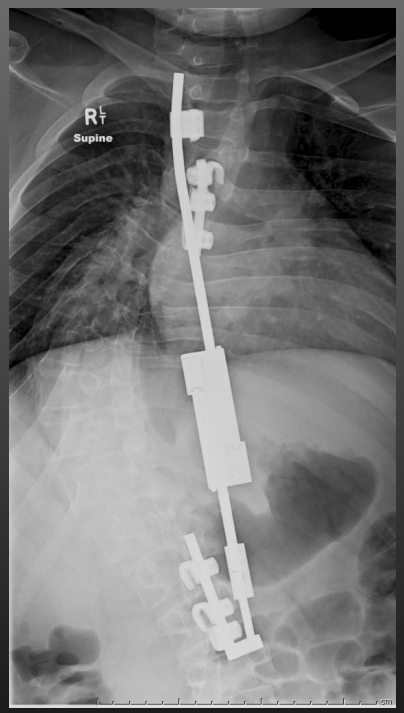
Hook dislodgement in 2 patients (of 13) avge. time over 2 years

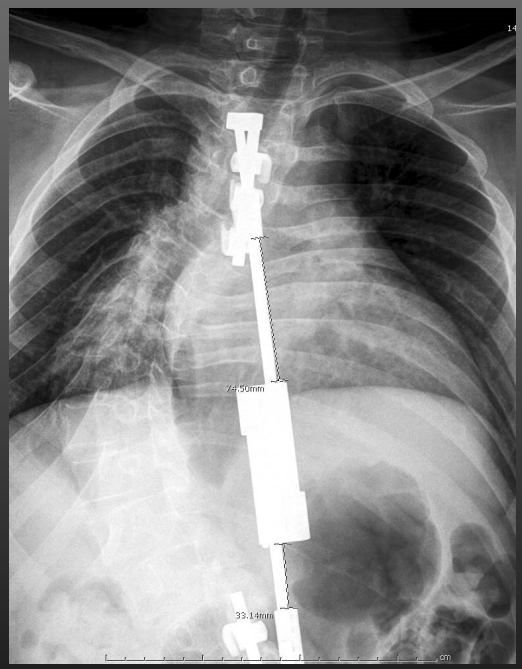
To Reduce Pullout – Build in a failure point

- Use of a soft rod to fail rather than disrupt the hooks/screws

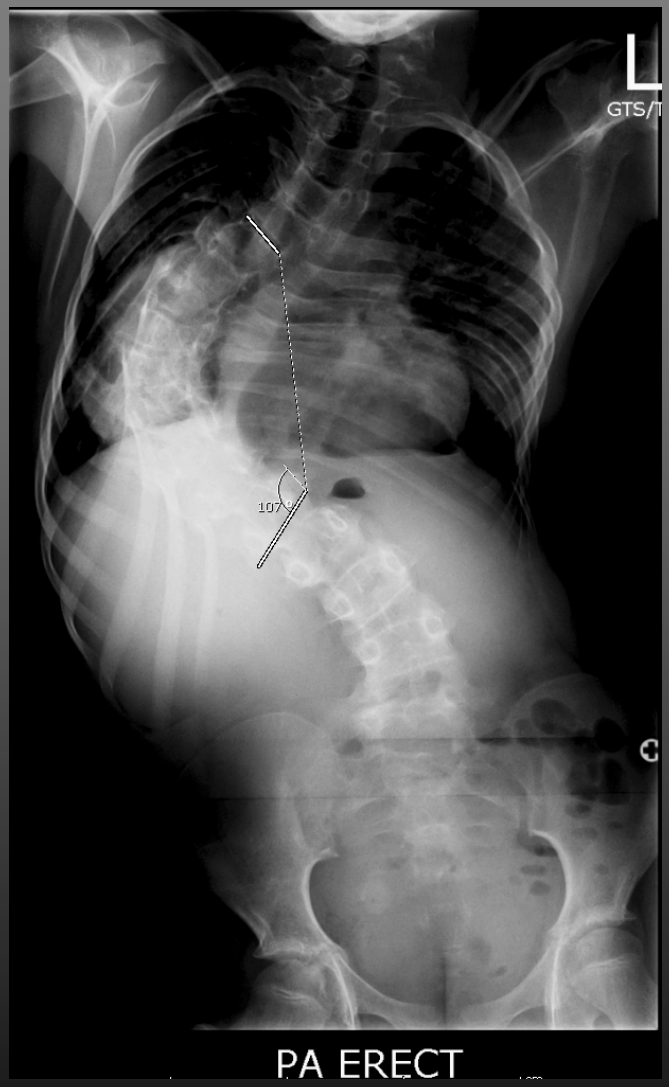


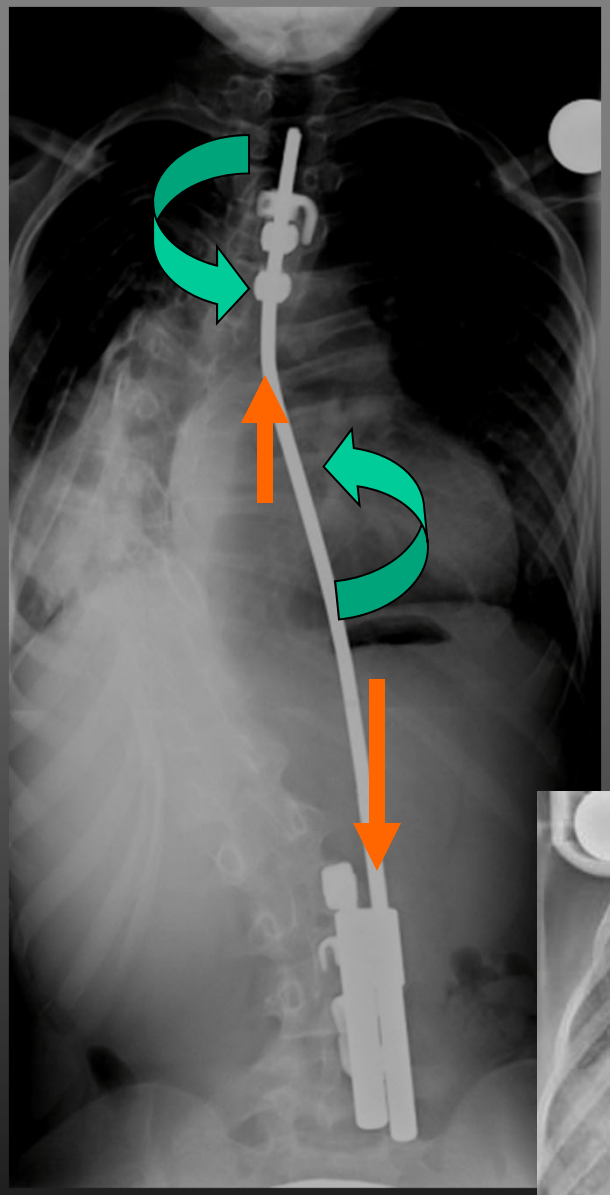


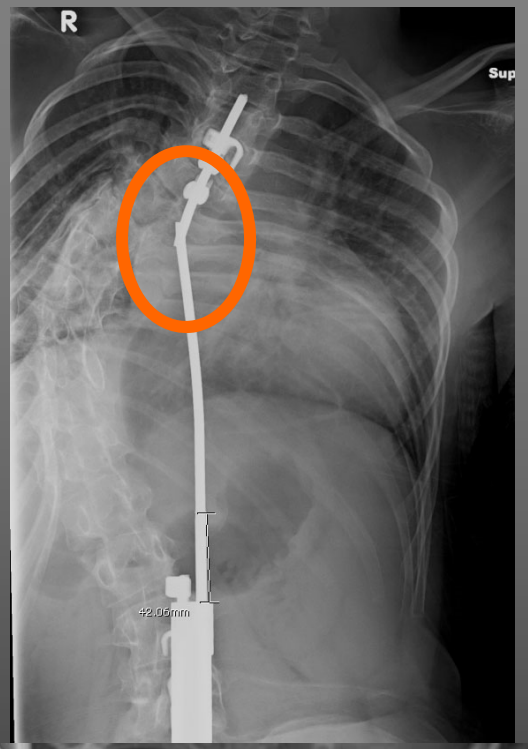


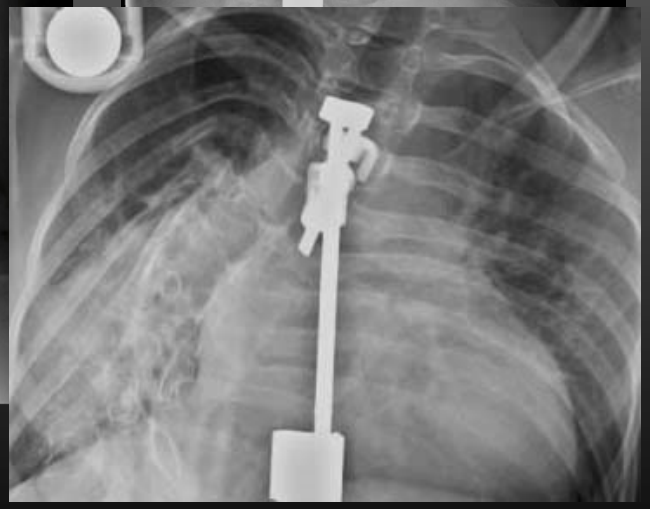


Autistic air guitarist –fracture of 5.5 titanium rod







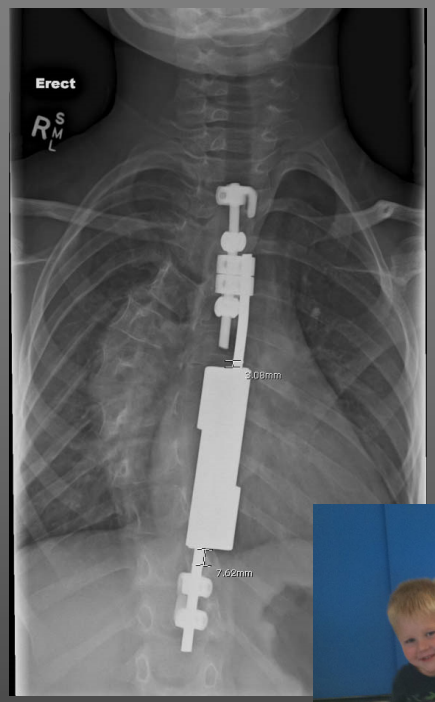


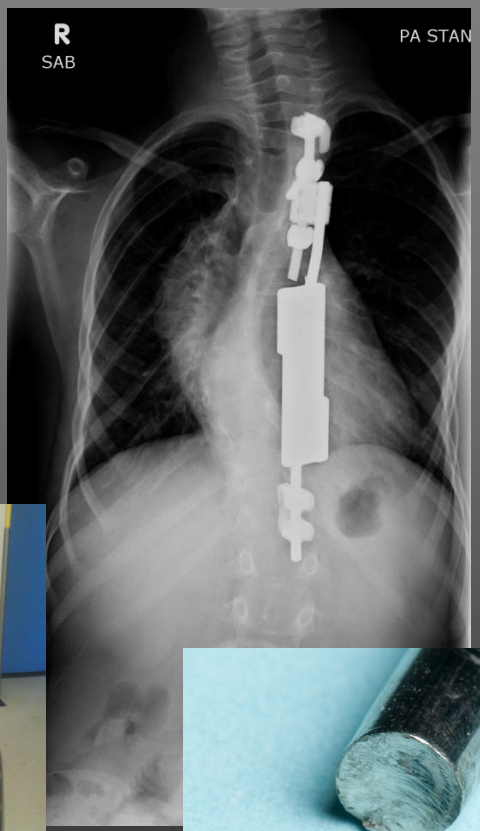
+45mm 18m.

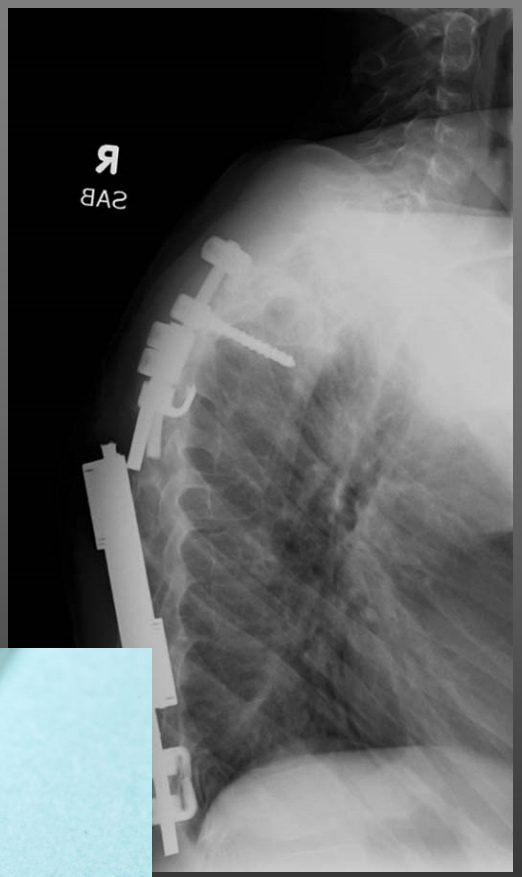
Rod Failures

- Version 1 rods – only 2 failures,
  - each after 18 months, 45mm & 30mm.
- Version 3 rods – 3 failures ,
  - all at marker ring,
  - Marker ring no longer used

Complication: Broken Rod at ring







- **Multiple fixation points (i.e good fixation) and large correction leads to fixation or rod failure**

V3 Rods

- All breaks are at the marker ring

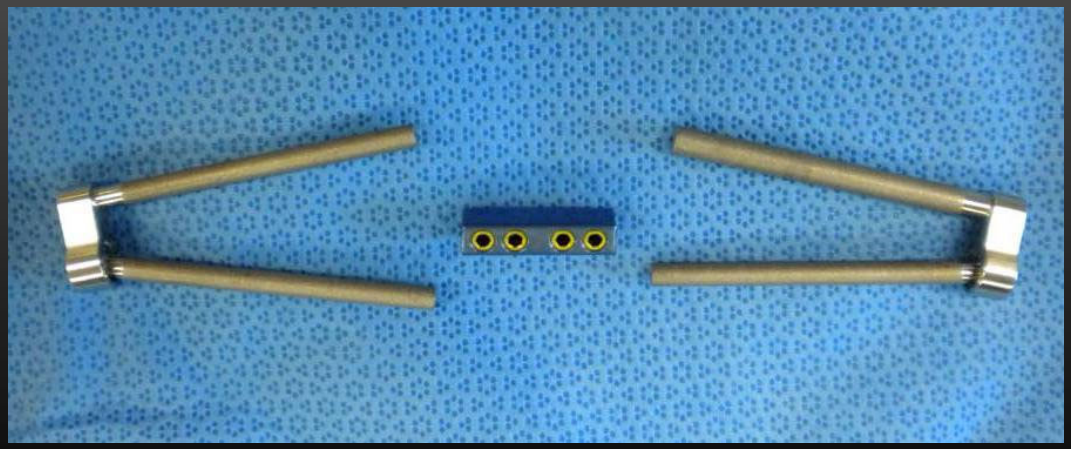
Current rods do not have this marker

The Relationship

- To lessen these induced forces, one must use a flexible rod or have a flexible connection between rod and fixation construct.

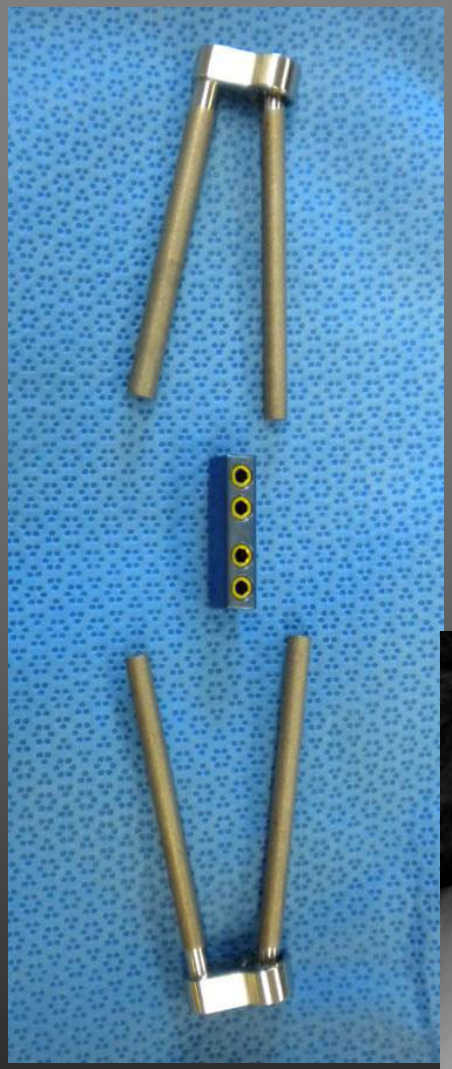
The Divorce Potential

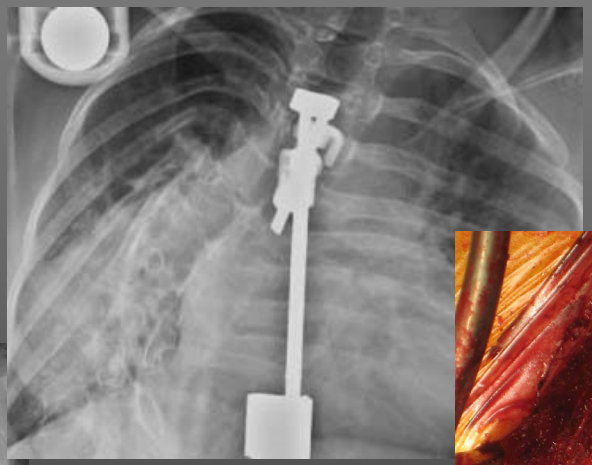
- There must be a relationship between correction of deformity, loads induced in the rod and loads induced on the fixation to the spine.
- Excessive loads may lead to rod breakage or fixation failure.
- Solution is to introduce flexibility and load dissipation into system

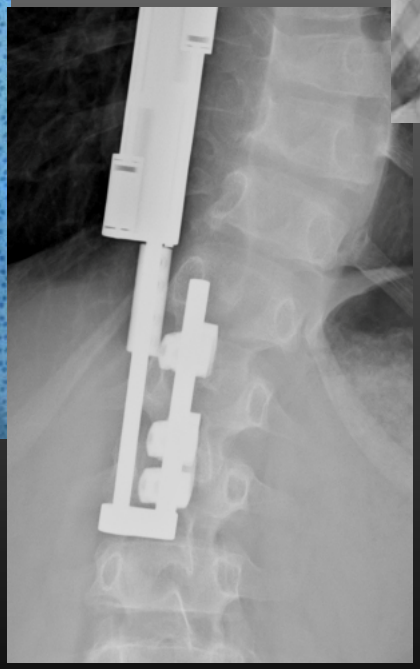


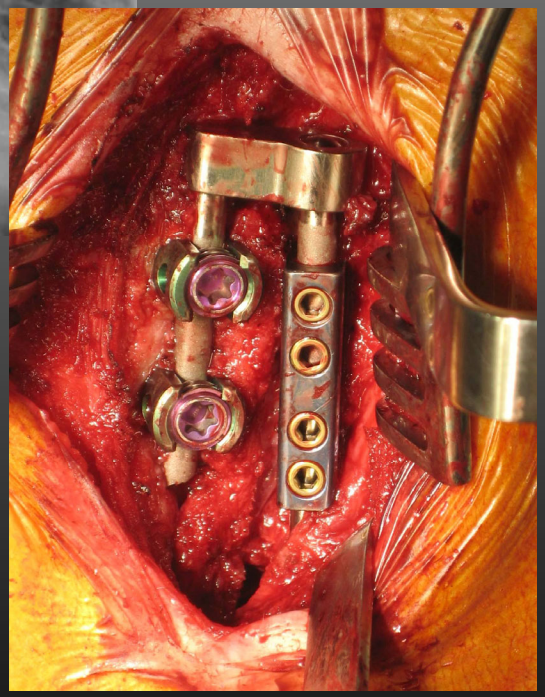
What happens if you push a mobile connector ???

Mobile Connector

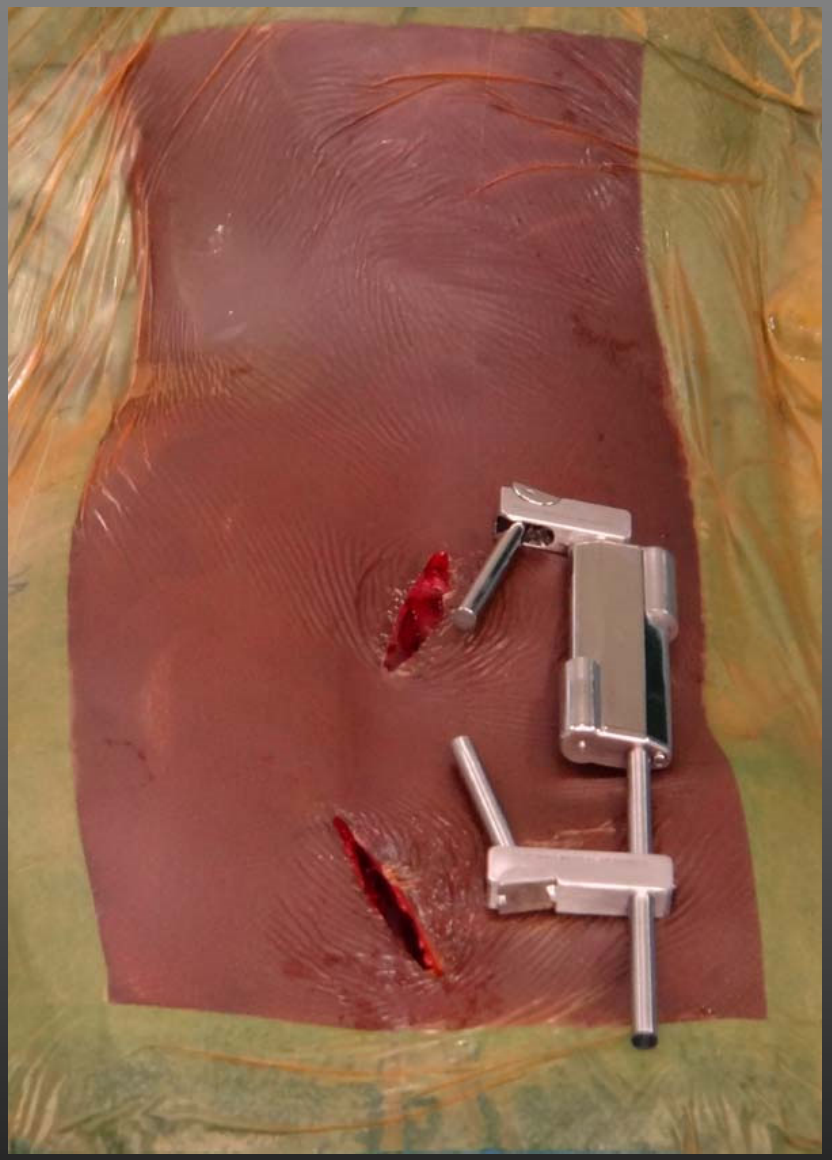








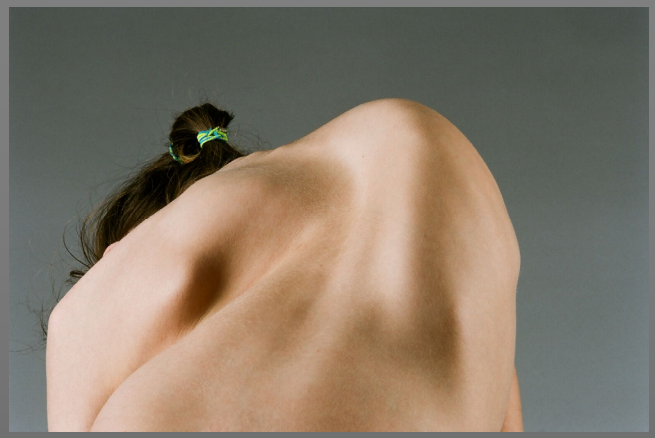
Set up in “pull” mode.



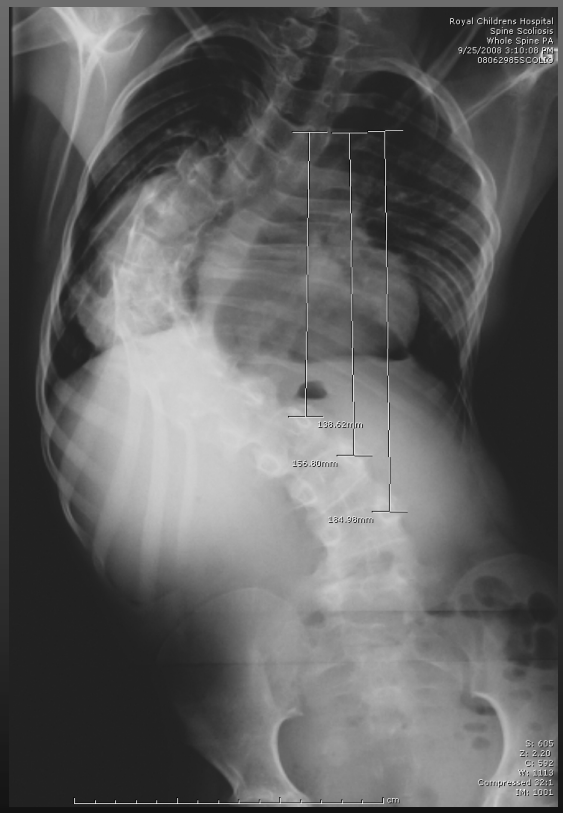
Patient of Acke Ohlin, Sweden.

Change in Body Shape

9 yrs

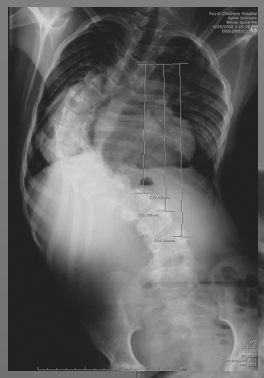


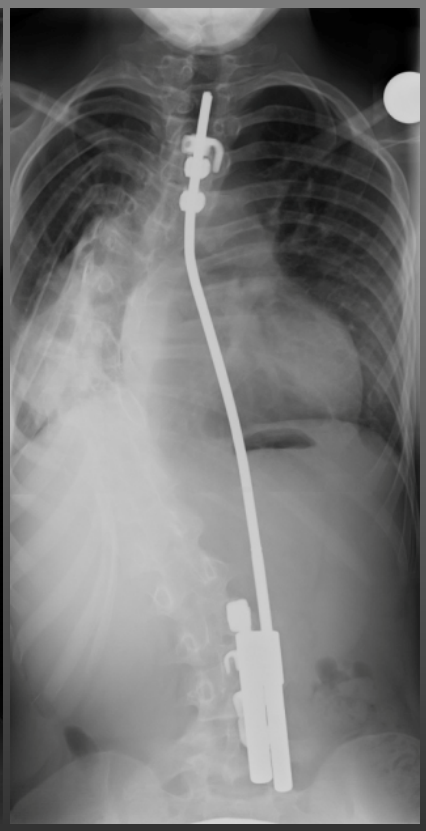
11 yrs

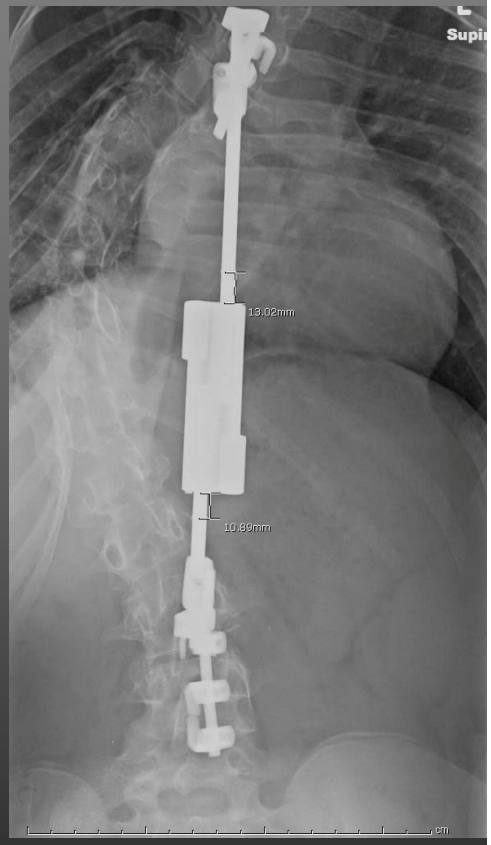


TN

Postop







11y7m

12y 10m

13y 5m 40mm

14y4m +23mm

Total to date 80mm


Bad Girl
BAD GIRL
TN

Patient	Cobb Start	Cobb Current	Length gained	Oper's after insertion	
1	82	59	20	2 Failed rod V2	
2	99/97	88/81	16	1 Failed parent/patient	
3	73	34	17	2	
4	94	57	20	2	
5	57	37	20	2	
6	77	45	23	0	
7	107	70	32	1	
8	76	42	65	3	
9	112	71	80	4	
10	98	45	90	2	
11	60	30	4	0	

Total Length Gained 387mm. Extra Operations 19

Unexpected bonus

- Major improvement in cosmesis and trunk shape with slow constant lengthening.
- Surprisingly low hook cut out rate with slow distraction (2 patients – after 3+ yr)
- Development of the mobile connectors has been a major advance

Summary:

While there have been mechanical teething problems, the gains in most patients have been significant with every expectation of more improvement to follow. This device is not a panacea for childhood spinal deformity but is a major step forward in management of these children.

Thankyou……