

# ***Construct Levels to Anchored Levels Ratio and Rod Diameter are Associated with Implant-Related Complications in Traditional Growing Rods (TGR)***

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SAN DIEGO CENTER  
FOR SPINAL DISORDERS



# Disclosure

- **Behrooz A. Akbarnia** - Nuvasive, K2M, DePuy Synthes (a), Nuvasive, K2M (d), Nuvasive (f), ISSGF, Nuvasive, K2M (g), GSF, SDSF, SOLAS (h)
- **John Emans** – DePuy/Synthes spine (a), DePuy/Synthes spine, Medtronic spine, Zimmer/Biomet (d)
- **Peter F Sturm** – DePuy, Medtronic, Nuvasive (d), Biomet (e), Journal of Children's Orthopaedics, Scoliosis Research Society, POSNA (h)
- **Paul D Sponseller** – DePuy Synthes Spine, Globus (a), Globus (d), JBJS deputy editor
- For the remaining authors none were declared.

(a) Royalties (b) Speakers bureau/paid presentations (c) Paid employee (d) Paid consultant (e) Unpaid consultant (f) Stock or stock options (g) Research support from a company or supplier as a PI (h) Board member/committee appointments for a society (i) Other financial or material support



# What we know in 2016

- Implant-related complications (IRC) are among the most common adverse events in TGR.

## IRC Risk factors include

- Bess et al. 2010

- 1) Age at the index surgery
- 2) Rod location (subcutaneous or submuscular)

- Yang et al. 2011

- 1) Rod metal type
- 2) Rod diameter
- 3) Rod location (subcutaneous or submuscular)
- 4) Ambulatory status
- 5) Amount of the curve correction at index surgery

- Schroerlucke et al. 2012

- Major curve size and maximum kyphosis angle ( $>40^\circ$  )



# Reported IRC

**Anchor risk factors, such as location of the anchors (rib vs spine) and adequate number of anchors have been previously reported**

Spine  
Deformity

[www.spine-deformity.org](http://www.spine-deformity.org)



Spine Deformity 2 (2014) 489–492

## Are Rib Versus Spine Anchors Protective Against Breakage of Growing Rods?

Kent T. Yamaguchi, Jr, MD<sup>a</sup>, David L. Skaggs, MD, MMM<sup>b,\*</sup>,  
Shaun Mansour, BA<sup>b</sup>, Karen S. Myung, MD, PhD<sup>b</sup>,  
Muharram Yazici, MD<sup>c</sup>, Charles Johnston, MD<sup>d</sup>,  
George Thompson, MD<sup>e</sup>, Paul Sponseller, MD<sup>f</sup>,  
Behrooz A. Akbarnia, MD<sup>g</sup>, Michael G. Vitale, MD, MPH<sup>h</sup>,  
Growing Spine Study Group

## Choice of Anchors – Rib vs. Spine: Importance of Proximal Anchor Number

Michael G. Vitale, Hiroko Matsumoto, Nicholas Feinberg, Evan Trupia, Matthew Shirley, Sumeet Garg, John Flynn, Peter F. Sturm, Francisco Sanchez Perez-Grueso, David P. Roye Jr, David L. Skaggs, and the Children's Spine Study Group and the Growing Spine Study Group

**Title:** Proximal Anchor Constructs in Early Onset Scoliosis Patients Treated with Growth Friendly Implants

How about: "Five or more Proximal Anchors including UEV Protects Against Reoperation"

**Authors:** Liam Harris BS, Lindsay M Andras MD, Gregory M Mundis MD, Paul D Sponseller MD MBA, John B Emans MD, David L Skaggs MD MMM, Growing Spine Study Group



# Purpose

This study attempted to look at the **entire GR construct** and foundation characteristics by thorough review of all radiographs to find any possible relationships with IRC.



# Methods

- **Study design:**

Retrospective review of a multicenter EOS database.

- **Inclusion criteria:**

- 1) age  $\leq 10$  years at surgery
- 2) spine-based dual TGR
- 3) minimum 2-year follow up
- 4) available imaging



# Methods

Cephalad and caudal foundations were grouped based on **number of anchor levels and anchor type.**

## Cephalad foundation

Anchor levels	2 levels	3 levels	>3 levels
Anchor types	Pedicles Screw (N=89; 32.4%) Hook (N=2; 5.5%) Mix (N=85; 30.9%)	Pedicles Screw (N=39; 14.4%) Hook (N=10; 3.6%) Mix (N=31; 11.3%)	Pedicles Screw (N=0) Hook (N=1; 0.4%) Mix (N=4; 1.5%)

## Caudal foundation

Anchor levels	2 levels	3 levels	>3 levels
Anchor types	Pedicles Screw (N=209; 76.2%) Hook (N=12; 4.4%) Mix (N=22; 8.0%)	Pedicles Screw (N=22; 8.0%) Hook (N=0) Mix (N=2; 0.7%)	Pedicles Screw (N=7; 2.5%) Hook (N=0) Mix (N=0)

**Note:** The decision on the current classification of anchor levels and anchor types was made Based on most prevalent levels and types in the current study in retrospect.



# Methods

- All radiographs were reviewed → cephalad and caudal foundation characteristics recorded.
- IRC was defined as:
  - 1) Rod fracture
  - 2) Anchor pull out
  - 3) Anchor prominence
  - 4) Anchor loosening
- Based on this review a “Construct Levels / Anchored Levels” (CL/AL) ratio was defined, which is the number of levels spanned by instrumentation divided by the number of levels with bone-anchor fixation.





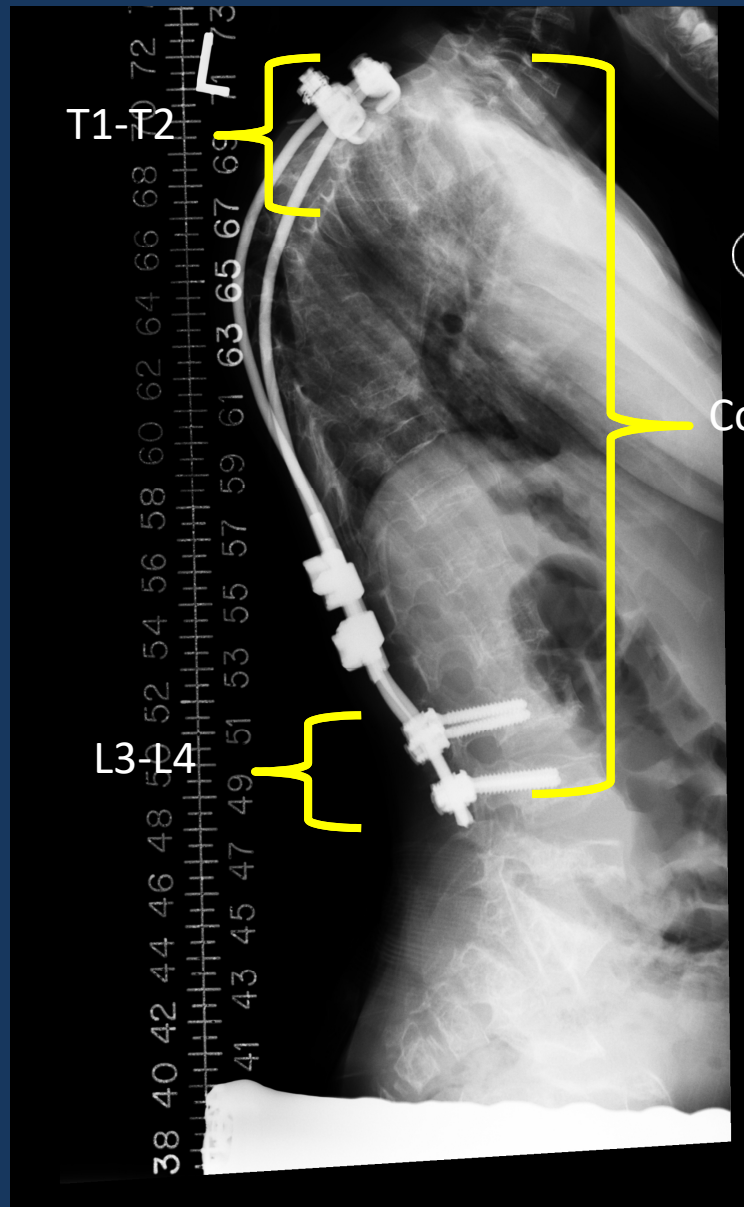
# New terms: CL/AL ratio & mirroring

Cephalad  
Anchored  
levels

2

Caudal  
Anchored  
levels

2



**CL/AL ratio= 16/4 =4**

Construct Levels 16

**No Mirroring:**

**Cephalad → Hooks**

**Caudal → Pedicle screws**

# Data collection

## Demographics:

- Gender
- BMI
- Etiology
- Ambulatory status
- Length of follow up

## Curve characteristics:

- Cobb angle
- Coronal alignment
- T1-S1 height
- T1-T12 height
- Max global kyphosis
- Lumbar lordosis
- Sagittal alignment

## Instrument characteristics:

- Rod diameter
- Metal type
- Rod location
- Connector type

## Foundation characteristics:

- Cephalad & caudal anchor type and levels
- Anchor density
- Anchor mirroring
- Pelvic fixation
- Cross link and location
- CL/AL ratio

## IRC:

- Type
- Time from index surgery
- Treatment



# Results

- 274 patients
- With IRC (n=140)
- Non-IRC (n=134)
- Mean follow up : 6.3 years
- (2.1-18.0 years)



# Results

	IRC	Non-IRC	P value
Age (years)	6.5	6.9	0.317
Gender (female)	75 (53.6%)	85 (63.4% )	0.111
BMI (kg/m <sup>2</sup> )	16.7	17.4	0.325
Ambulatory Stat (mobile)			0.153
Etiology	idiopathic (25%), neuromuscular (24%), syndromic (16%) congenital (11%) 24% no etiology recorded	neuromuscular (37%) idiopathic (18%), congenital (11%), syndromic 10% 24% no etiology recorded	0.273
Primary curve (°)	73	77	0.109
T1-S1 height (mm)	266	266	0.393
Coronal alignment (°)	25	30	0.598
Sagittal alignment (mm)	20	22	0.941
Kyphosis (°)	55	46	0.014



# Rod diameter

Rod diameter	Non-IRC (117/134)	IRC (126/140)	P value = 0.022
< 4 mm	18 (15.4%)	29 (23.0%)	
4-5 mm	78 (66.7%)	88 (69.8%)	
≥ 5 mm	21 (17.9%)	9 (7.1%)	

Rod diameter was available in 117/134 non-IRC and 126/140 IRC group.

Both univariate and multivariate analysis showed IRC occurs more frequently in smaller diameter rods (< 5 mm)



# Construct characteristics

## No difference after univariate and multivariate analysis

- Connector type
- Cross link presence
- Cross link location
- Mirroring
- Pelvic fixation
- No. of cephalad construct
- Density of cephalad construct
- Density of caudal construct

## Different after Univariate analysis but no difference after multivariate analysis and after controlling for kyphosis and rod diameter

- No. of cephalad levels
- No. of caudal levels
- No. of caudal constructs



# Foundation Type & Configuration

- Univariate analysis showed **3 levels** and more both at cephalad and caudal region are better. However, After multivariate analysis and **controlling for kyphosis and rod diameter** there was no difference ( $p > 0.05$ )
- **Anchor types** (Pedicle screw, hook, mix) made no difference both after univariate or multivariate analysis.

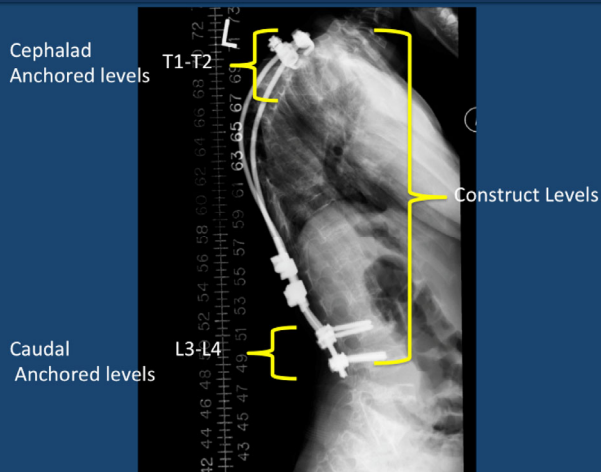


# But ! CL/AL ratio

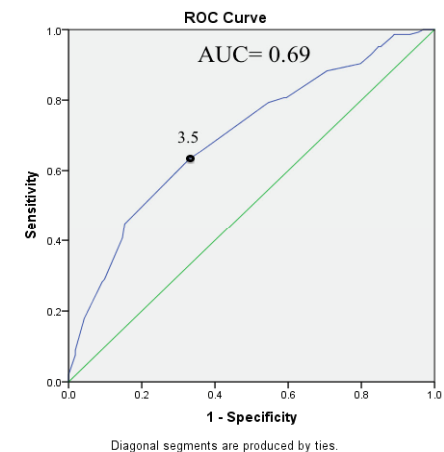
Receiver Operating Characteristic (ROC) curve showed **3.5** is cut off point for CL/AL ratio. → It implies that constructs with CL/AL > 3.5 are at higher risk of having IRC.

**ROC definition:** ROC is a graphical plot that illustrates the performance of a binary classifier system as its discrimination threshold is varied. The curve is created by plotting true positive ratio (TPR), against false positive ratio (FPR), at various threshold settings.

Both univariate and multivariate analysis showed  
**CL/AL > 3.5 increases the IRC risk.**



Complication				
	No	Yes		
CL/AL < 3.5	88 (66%)	48 (34%)		
CL/AL ≥ 3.5	46 (34%)	92 (66%)		
Univariate analysis				
	OR	Lower	Upper	<i>p</i>
CL/AL <3.5	1			
CL/AL ≥3.5	3.67	2.23	6.04	<0.001
Multivariate analysis				
	OR	Lower	Upper	<i>p</i>
CL/AL <3.5	1			
CL/AL ≥3.5	3.43	1.89	6.24	<0.001



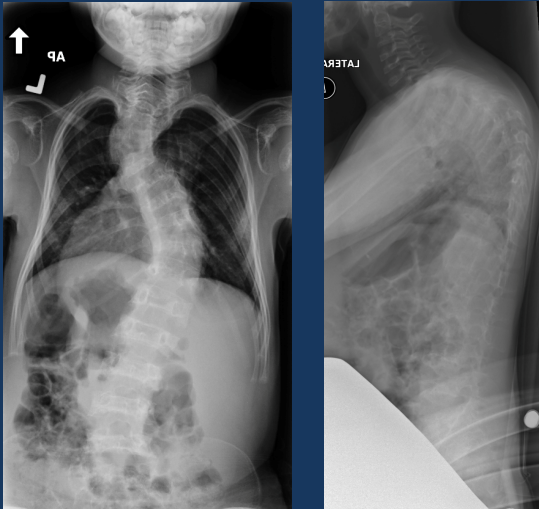


# Conclusion

While patient characteristics like **kyphosis** have been proven to be associated with implant failure, it is a combination of characteristics that include **rod diameter** and **CL/AL ratio** that showed significant correlation with IRC.



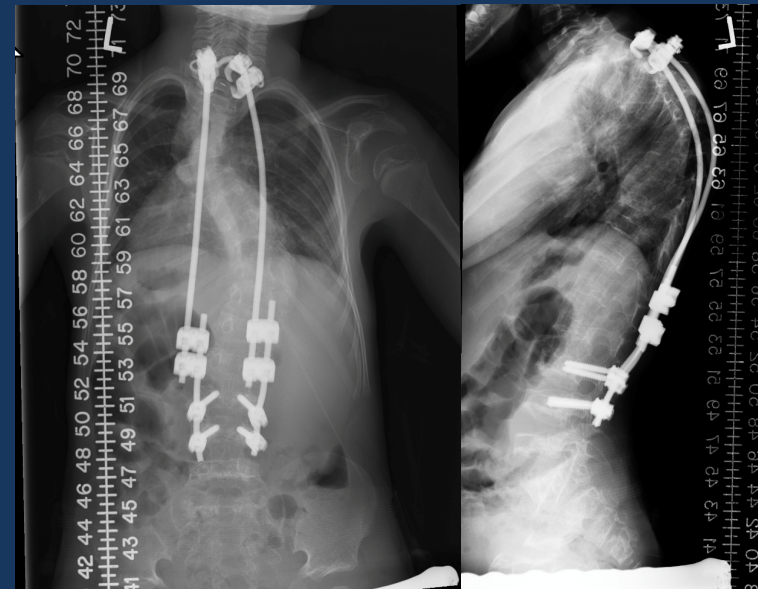
# Lets revisit our case!



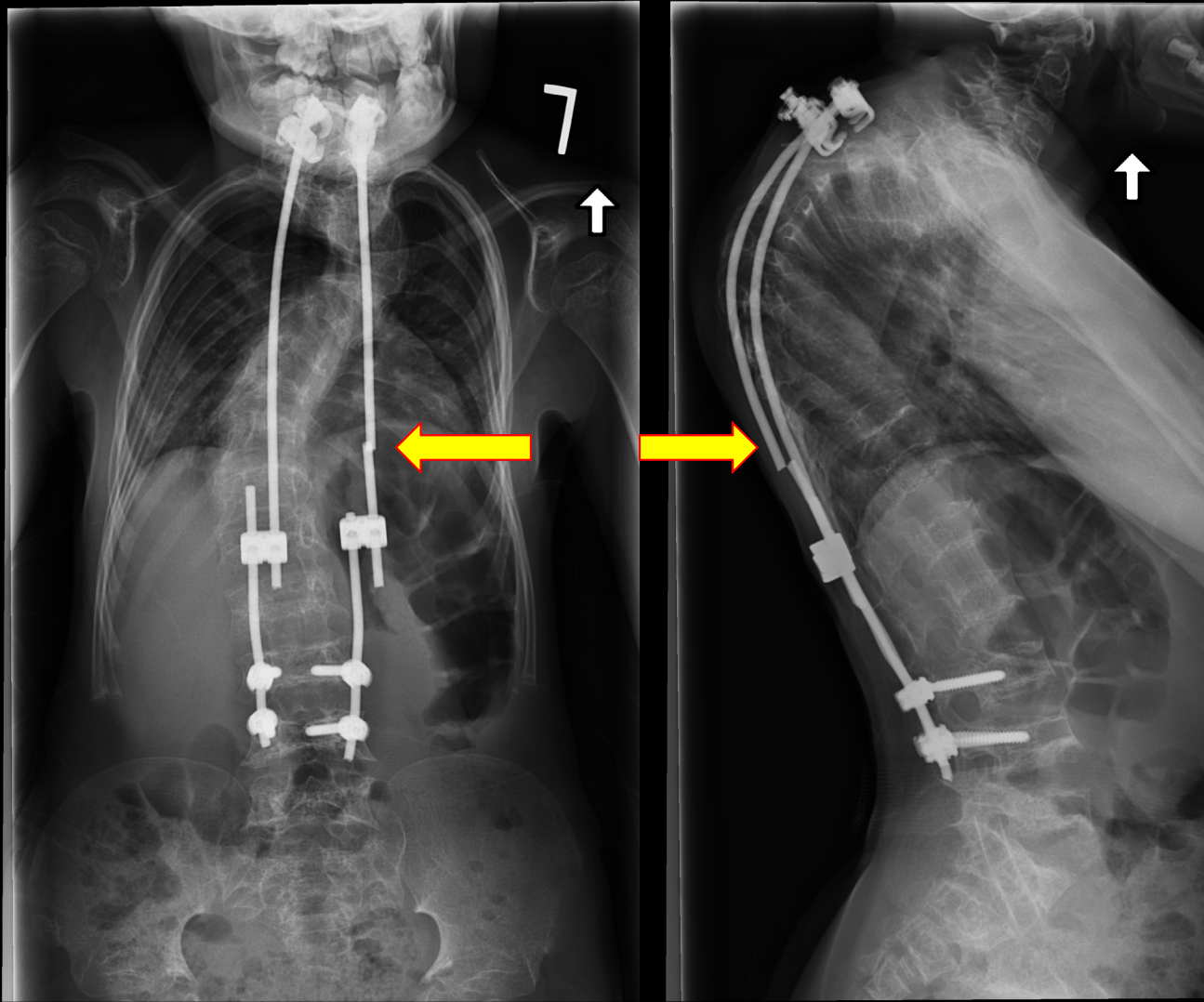
5+3 Female ,Idiopathic  
BMI 15.6  
Mobile  
Primary T7-L2 curve  $\rightarrow 52^\circ$   
T1-T7 curve  $\rightarrow 49^\circ$   
RVAD  $35^\circ$  phase I  
Max Kyphosis  $\rightarrow 90^\circ$   
Coronal balance  $\rightarrow 10$  mm  
T1-S1  $\rightarrow 210$  mm  
T1-T12  $\rightarrow 110$  mm

## TGR

T1-T2: All hooks  
L3-L4: All PS  
Side to side wedding band  
No Cephalad cross link  
Titanium rod 3.5 mm  
Subcutaneous  
Postop TLSO  
Kyphosis  $\rightarrow 90^\circ$   
 $CL/AL = 16/4 = 4 > 3.5$



# Three red flags ! → it will fail



**Twice rod  
fracture 3 years  
Later which  
required  
rod exchange**



# future

It is recommended to validate the proposed **CL/AL ratio** in future studies.

- Also, future IRC studies to include the **entire image** both at cephalad and caudal regions.



# Take home message

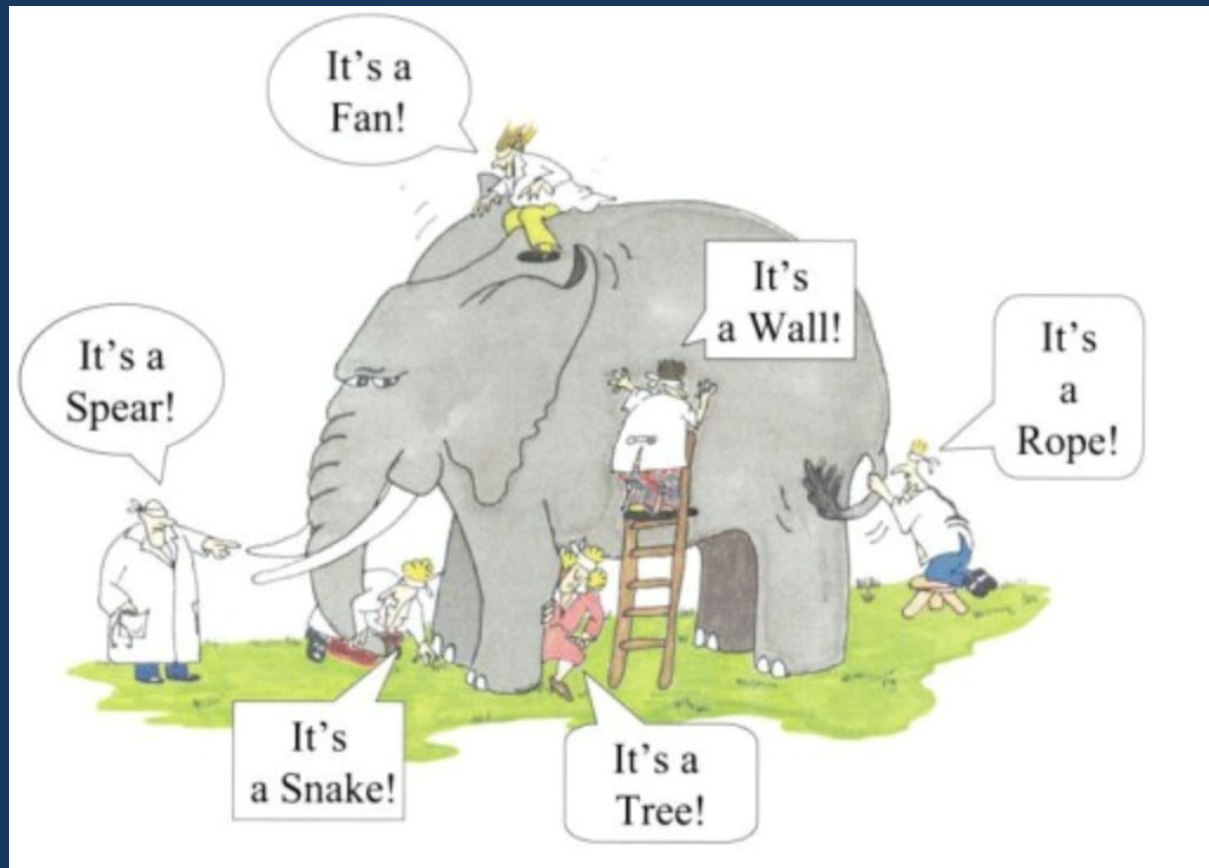
In addition to patient characteristics, consideration of length of construct to number of anchored levels ratio (CL/AL ratio) and rod diameter is advised to be a part of preoperative planning to minimize implant-related complications.

Also, future IRC studies it is suggested to include the **entire image** both at cephalad and caudal regions.



# Define elephant in darkness

**We may need to study the construct in its entirety!**



# Thank you