

Loss of Fixation of Upper Thoracic Pedicle Screws Causing Spinal Cord Injury

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John Purvis, John Smith, David L. Skaggs

Growing Spine Study Group



Previous Study:

Safety of Pedicle Screws Vs. Hooks in Growing Rods

- Retrospective study - GSSG database
- Only complications *directly* attributable to screw or hook from index surgery



From GSSG database

	896 Screws	867 Hooks
#complications	22 (2%)	60 (7%)
Acute loss of fixation	4	35
Migration	14	22
Breakage	1	0
Skin breakdown	2	0
Unspecified	1	3
Neurologic	0	0
Vascular	0	0



Methods of this Study

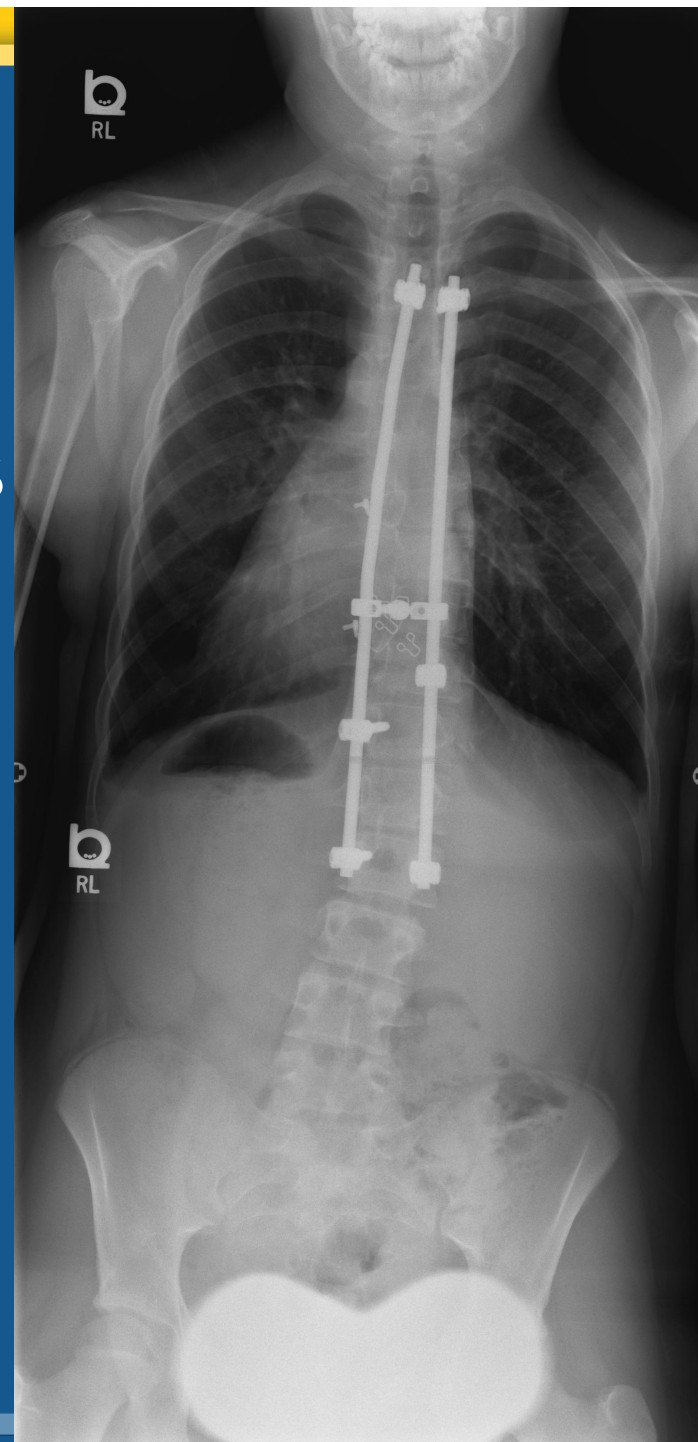
Informal polling of SRS and POSNA
members of thoracic pedicle screws
causing cord injury

3 cases submitted



Common Findings

- 1-2 pedicle screws at top
- > 5 vertebrae below top screws without other screws



Case 1 Growing Rod

2 yr s/p initial surgery
3 uneventful lengthenings

2 screws T2

Next screw T10

9/06

9/08



SG
Study Group

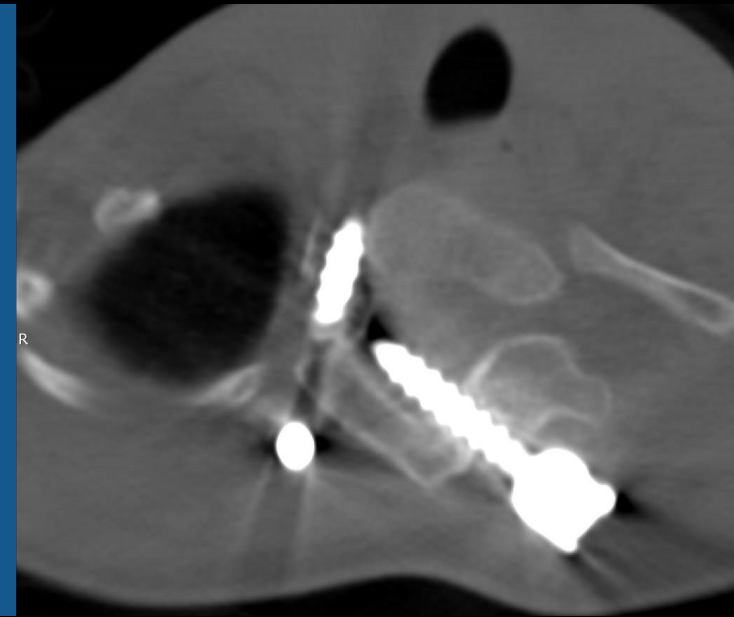
Case 1 Growing Rod

2 screws T2

Next screw T11

9/06

9/08

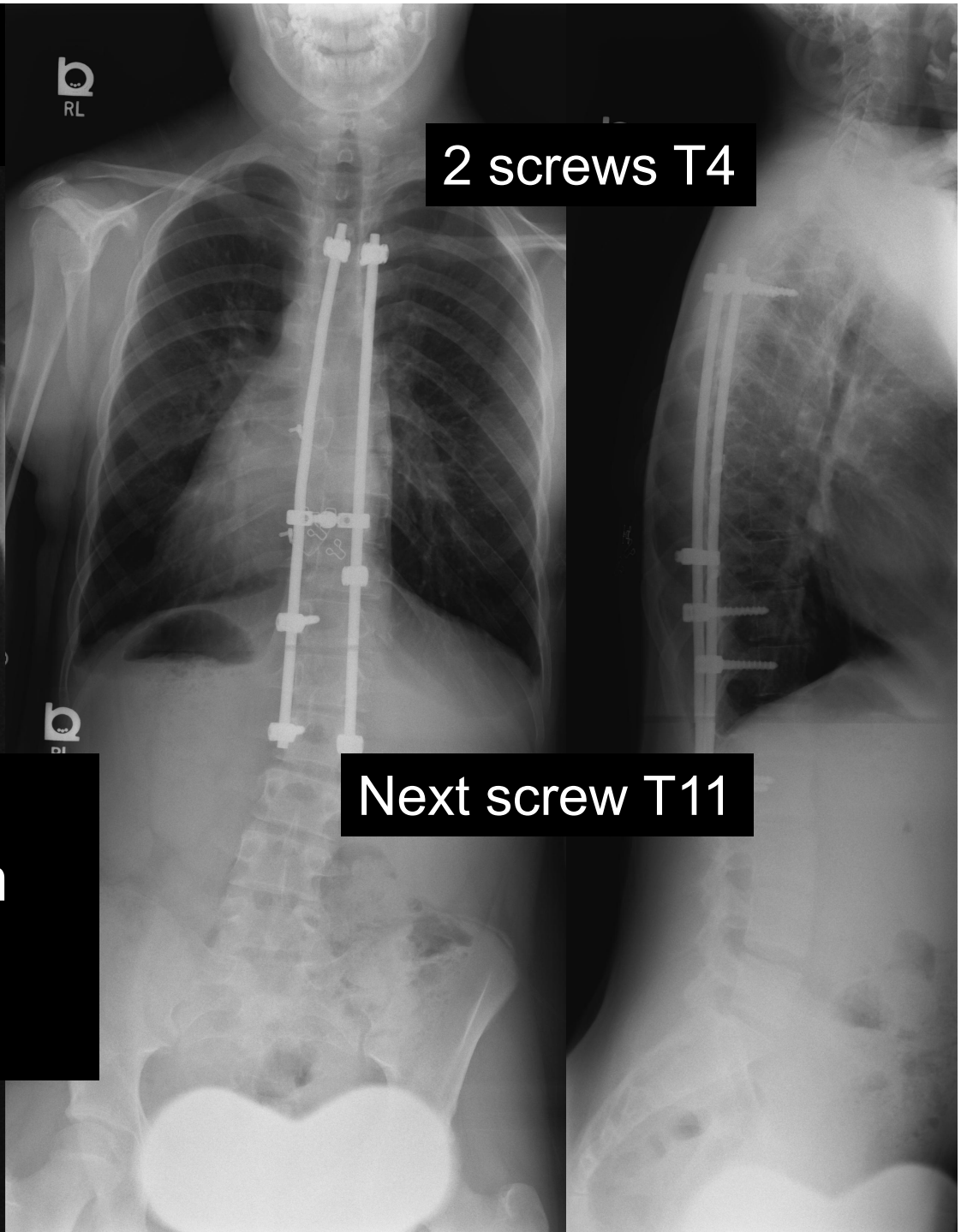
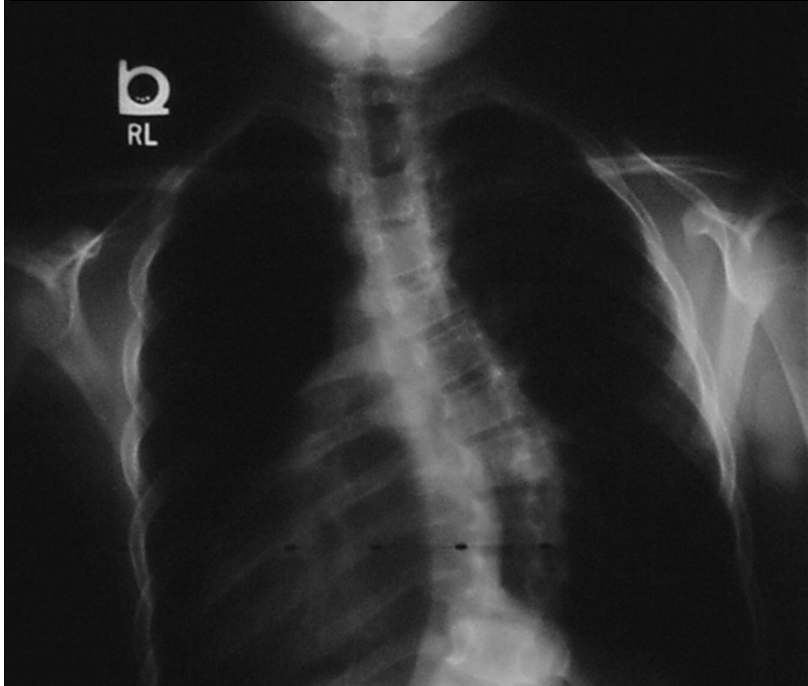


3 days after lengthening
Spastic paraparesis
Thoracic level sensory loss



SG
Study Group

Case 2: 13 yo



2 screws T4

Next screw T11

Attempted fusion
18 mo post-op fell down
Severe LE weakness
Unsteady gait

Series 3

CT THORACIC SPINE W/O



10 cm

Case 2: 13 yo

T4

L

STANDARD

Attempted fusion
18 mo post-op fell down
Severe LE weakness
Unsteady gait



Case 3: 23 yo Anglemens Syndrome

Single screw T4

Attempted fusion
1 mo after surgery,
pain, leg weakness

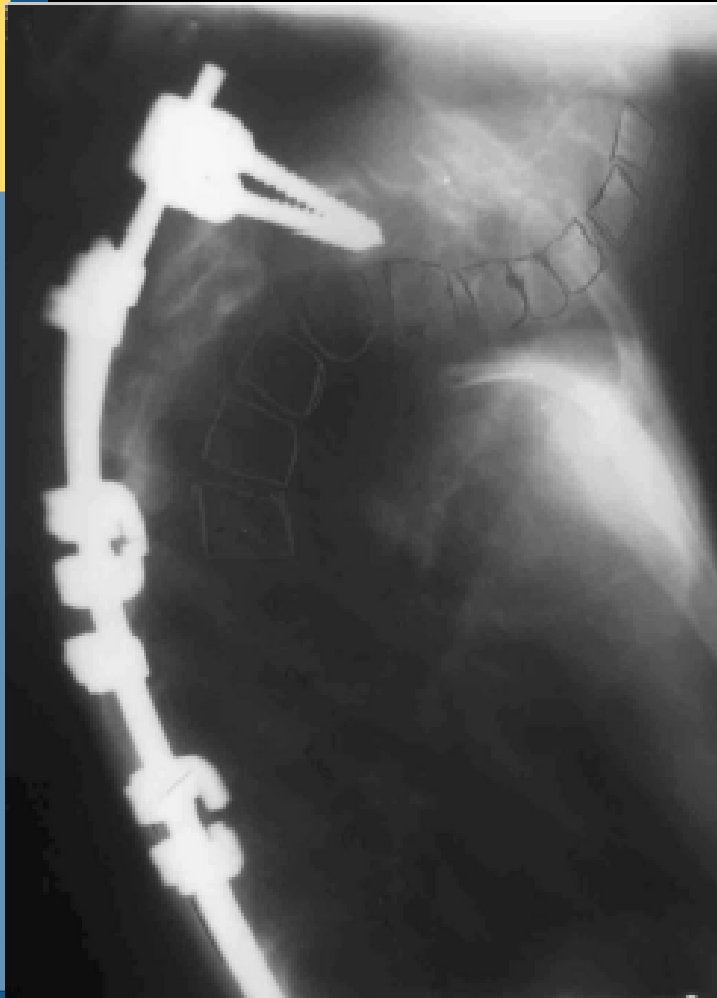
Next screw T12

4095 [4094]
4047 [4042] JS

Case 4 Alanay, Yazici, Spine 2003

6 yo girl PSF

3/5 LE weakness - clonus- difficulty walking



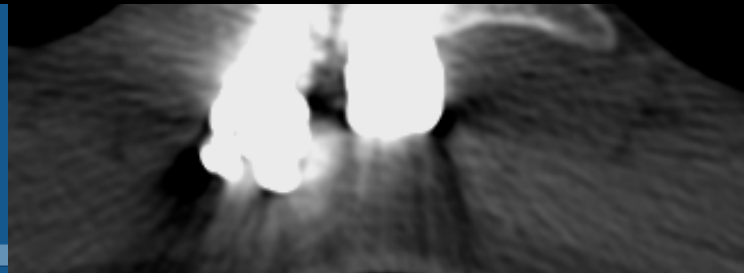
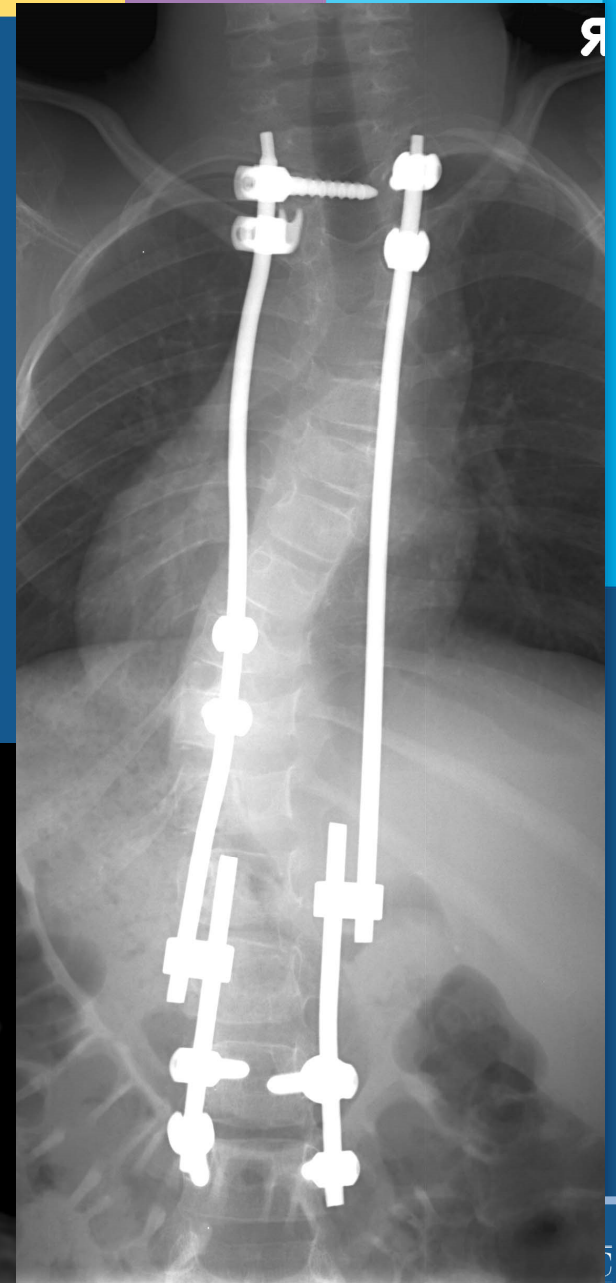
Common Findings

4 cases

- 1-2 pedicle screws at top
- > 5 vertebrae below top screws without other screws

Conclusions?

Use hooks if not at least 3-4 screws?



Thank You



Conclusions ???

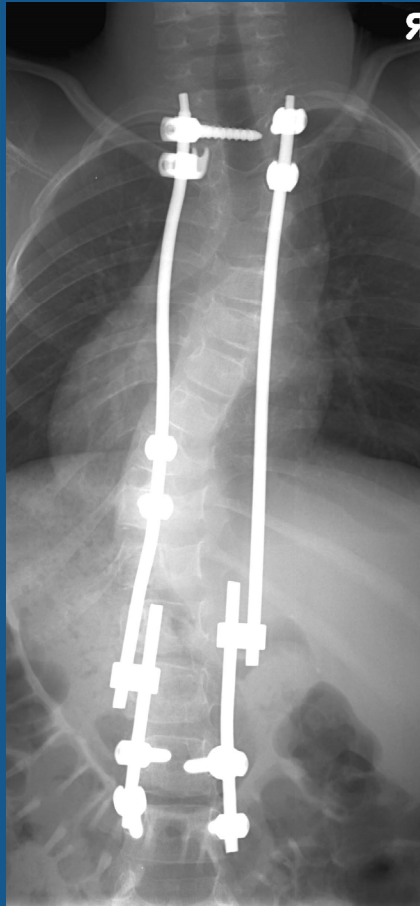
If only 1-2 pedicle screws can be placed at the cephalad half of long spinal constructs

Perhaps use hooks which would fail posteriorly with less risk to the spinal cord.



Anecdotal Case – Not in this study

Paralysis 2 yr after initial survey



Opinion:
Minimum 4 pedicle
screws for upper
anchor

Thank You



Previously Published Case

Opinion:

Minimum 4 pedicle screws for upper anchor

896 Screws

867 Hooks



Neurologic

0

0

Vascular

0

0



Thank You



SSG

Growing Spine Study Group

Children's
Hospital
LOS ANGELES

CHILDREN'S
ORTHOPAEDIC CENTER

USC
UNIVERSITY
OF SOUTHERN
CALIFORNIA

Significance

If pedicle screws have 1/3 the complications of hooks, then the FDA should consider screws safe in the immature spine.



References

- Akbarnia, B. A., M. A. Asher, et al. (2006). Complications of dual growing rod technique in early onset scoliosis: can we identify risk factors? Annual Meeting of the Scoliosis Research Society, Monterey, CA.
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Safety of Pedicle Screws Vs. Hooks in Growing Rods

David L. Skaggs
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Behrooz A. Akbarnia
Growing Spine Study Group



Pedicle Screws NOT FDA Approved in Immature Patients

- Must prove **safety** and efficacy

Anchor failure common
in growing rods...
Ideal for evaluation



Discussion: Legal Opinion

Kathleen McDermott, JD
Former Federal Prosecutor

FDA off-label usage permitted if

- In patients best interest
- Supported by peer-reviewed information

Orthopaedics Today, Sept 2010



Methods

Retrospective study

247 patients, 18 institutions

Inclusion criteria:

- Children <10 years
- Growing rods
- 1998-2008

Only complications *directly*
attributable to screw or hook
from index surgery

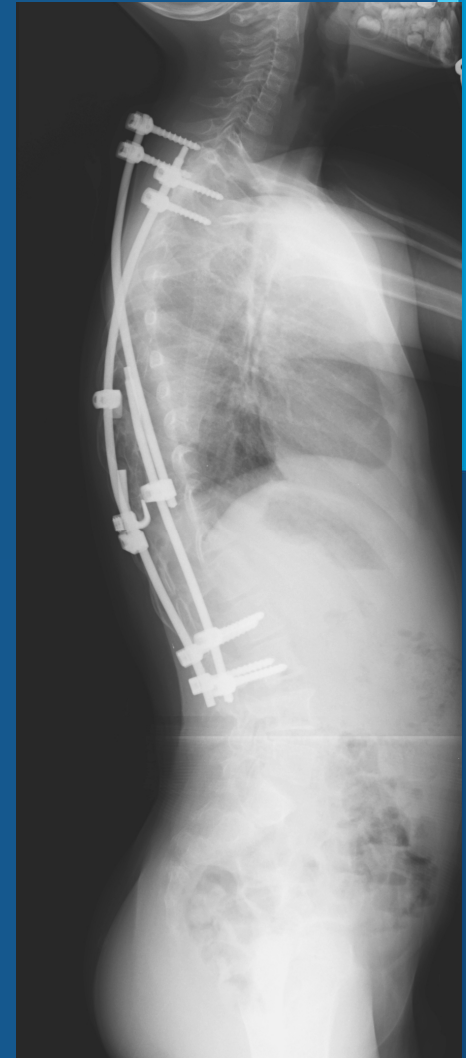


Results

Age at index surgery = 5.2 years

Mean f/u = 40 months

Loss of fixation for both screws and
hooks = mean 19 months



Results: 247 patients

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Limitations

Retrospective database study

Did not differentiate b/w upper thoracic and lumbar positions

Only 40 months mean f/u



Conclusions

Pedicle screws in growing rods have significantly less complications than hooks ($p < 0.001$)

	896 Screws	867 Hooks
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If pedicle screws have 1/3 the complications of hooks, then the FDA should consider screws safe in the immature spine.

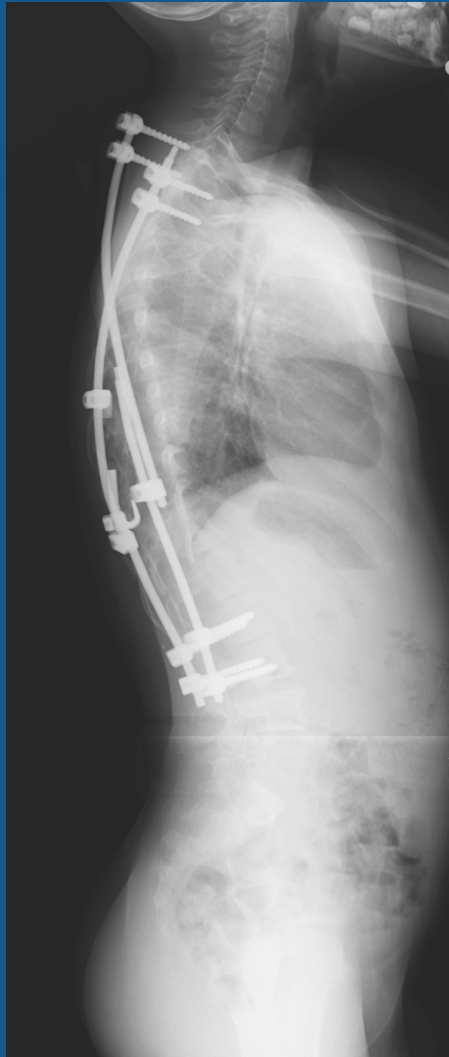


The Growing Spine Foundation is supported primarily by donations from its surgeon members and also from unrestricted grants received either directly, or, through OREF by industry and other organizations, including K2M, DePuy Spine, Stryker Spine, Globus Medical and the Scoliosis Association of San Diego.

The Growing Spine Foundation acknowledges the support and thanks all donors who supported its cause.



Pullout w/o injury



ESSG
Lower Spine Study Group

hook pullout



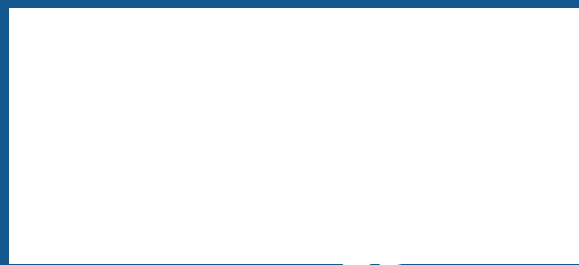
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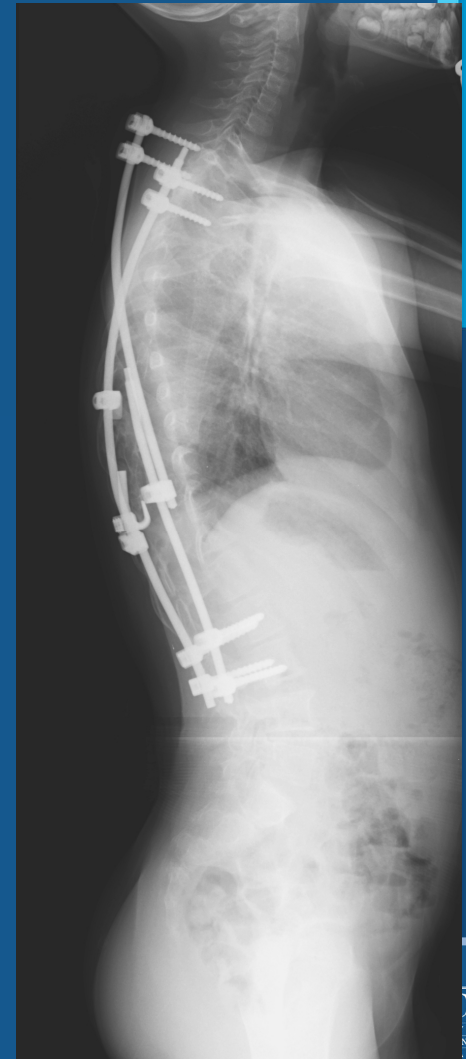
7% (60/867) Hook Complications

- 35 acute loss of fixation
- 22 migration over time
- 3 unspecified loss of fixation



2.4% (22/896) Screw Complications

- 4 acute loss of fixation
- 14 migration over time
- 1 breakage
- 2 skin breakdown
- 1 unspecified loss of fixation



Disclosures

- a. Grants/Research Support
- b. Consultant
- c. Stock/Shareholder
- d. Speakers' Bureau
- e. Other Financial Support

David Skaggs, MD	Medtronic (b,d); Stryker (b,d)
Karen Myung, MD	None
Charles Johnston, MD	Medtronic (a,b,d,e)
Behrooz Akbarnia, MD	Allez Spine (c); Axial Biotech (a); DePuy (a,b,e); Ellipse Technologies (b); K2M (b,d,e); Medtronic (a); Nuvasive (a,b,c,d); (d)
	Stryker



State of the Art Scoliosis Surgery: What I Would Really Want for My Daughter

David L. Skaggs, MD
Professor and Chief
Children's Hospital Los Angeles
University of Southern California



Disclosure

1 Growing Spine Study Group Board

2,3 Lippincott, Williams & Wilkins

3, 4, 5a Medtronic

4, 5a Stryker Spine

I did not develop nor receive royalties from any derotation device.



Thank you



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