

Pedicle Screws have Less Complications than Hooks in Children \leq 10 Years Old with Growing Rods

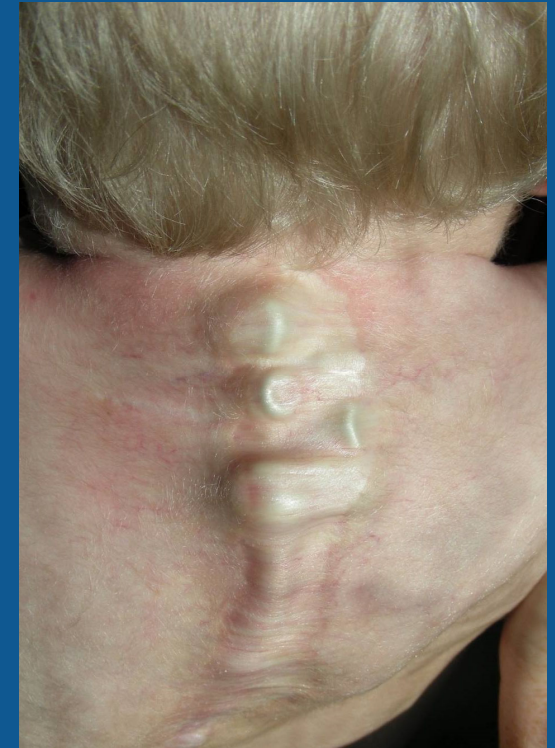
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Pedicle Screws NOT FDA Approved in Immature Patients

■ 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



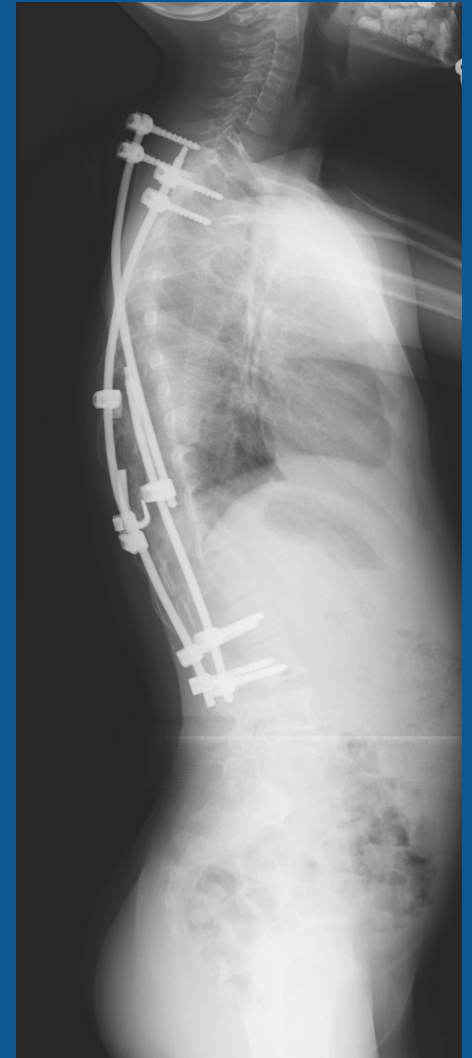
Methods

- 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

	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


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Previously Published Case

Opinion: Minimum 4 pedicle screws for upper anchor	896 Screws	867 Hooks
		
Neurologic	0	0
Vascular	0	0

Limitations

- Retrospective database study
- Did not differentiate b/w upper thoracic and lumbar positions
- Only 40 months mean f/u

Conclusion: 247 patients

- Pedicle screws in growing rods have **~3X** less complications than hooks ($p < 0.001$)

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THANK YOU

- *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.*

