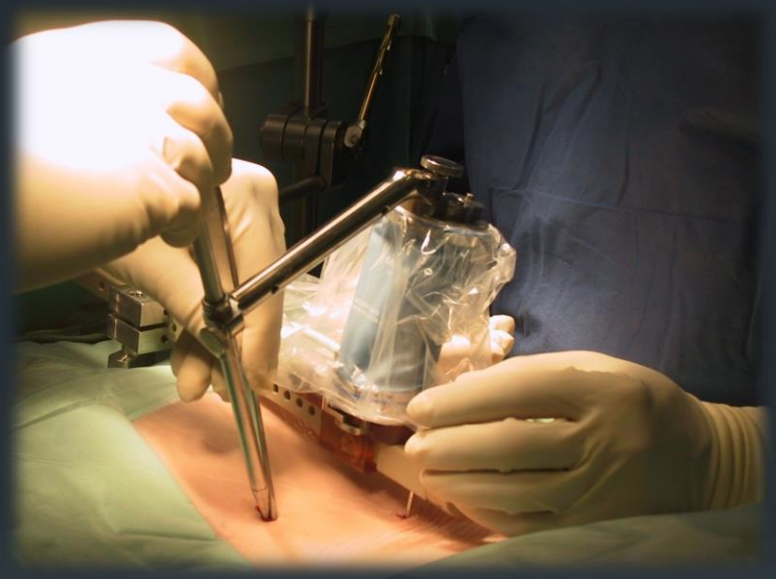
Robotic Guidance in Spine Surgery



Dennis P Devito MD

Director Spine Program

Children's Healthcare of Atlanta

Why embrace this technology ?

To add a new dimension of safety and precision to the way spinal implants are currently inserted in <u>scoliosis</u>, and other spinal surgeries

How many times and ways I tried to answer this question .....?

- Stereotactic guidance, not navigation (not virtual)
- More accurate
- Pre-operative planning and preparedness
- Efficient work flow
- Less intra-operative radiation
- Reproducible results, and reasonable learning curve
- “ Why not use glasses if they help you see better ?”
- Practice builder

Robot acceptance very slow and gradual

Presentation goals:

- discuss personal experience in spinal deformity

- present objective, reviewed data

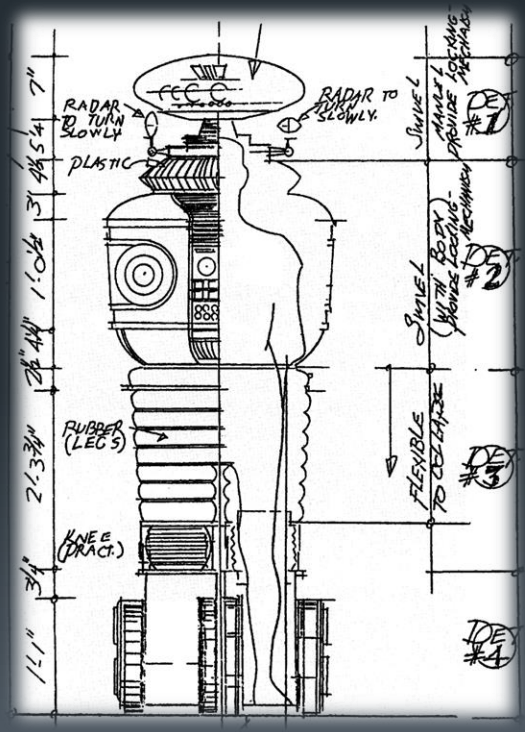
- answer questions about robotic guidance

No one seems to mind riding around in cars that have been put together by robots…

The beginning - SpineAssist

- **<u>2006</u>** – introduction to robot guidance technology (SpineAssist)
  - Eli Zahavi: brainstormed ideas on application to spinal deformity (pediatric scoliosis) from a MIS platform

'new design'



- **3 active** robot stations in the US; **~ 100 cases**
  - Adult degen./deformity cases (Cleveland, San Diego)
  - CHOA – peds scoliosis deformity center (Atlanta)
  - **Initial learning curve ➡ 6 software revisions**
  - **accommodate complex spinal deformity**
- **<u>2016</u>** – Renaissance platform (and Mazor X)
  - **70 robotic stations** in US (113 global); **16,000 cases worldwide**

My background - implant placement

- Anatomic ‘free-hand’ technique for many years…
  - Relatively fast
  - No adverse outcomes
  - Reasonable accuracy
    - few revisions
    - ‘navigation’ not helpful
  - **never actually scientifically reviewed my freehand accuracy**

Computer Assisted Robotic Guidance

Goals:

- Improve accuracy screw placement – raise confidence and safety in difficult areas of the spine (thoracic)

-make it better th
!

- Reduce radiation exposure /risk
- Preserve standard operative time
  - improve screw insertion times, esp. in cases of difficult anatomy
- Maintain small OR footprint

“medical robotics allow surgeons greater access to areas under operation using more precise methods”

Is this true?

Value of clinical research

- Foresight to prospectively collect data on all cases
- Document and measure results without bias
- Summarize and report results to the scientific community
  - **get on the podium !**

2007 – 2011 at CHOA (Scottish Rite): results review

- IRB approved review of <u>120 adolescent scoliosis</u> cases

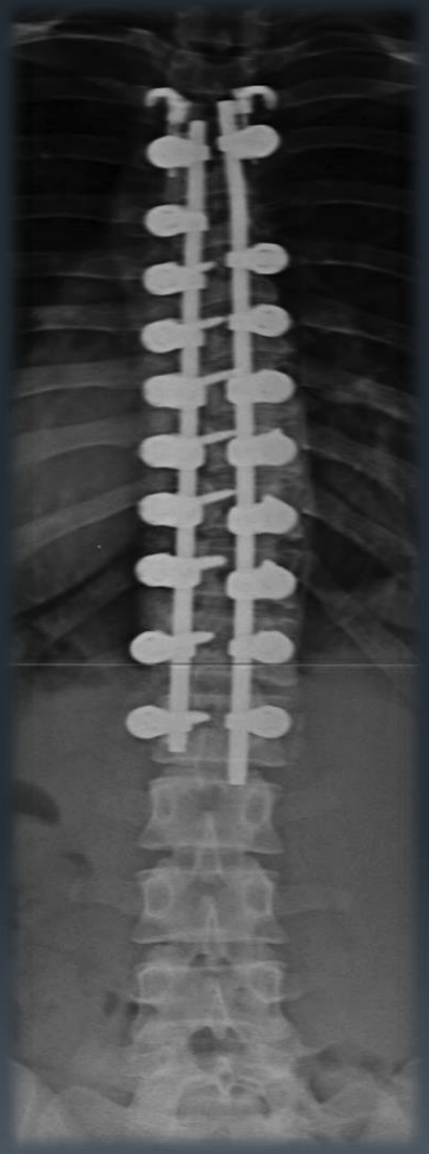
- **Assess the value of image based robotic- guidance**
  - **- pre-operative planning tool**
  - **- reproducible and consistent operative results**
  - **- reduce screw misplacements – document accuracy**

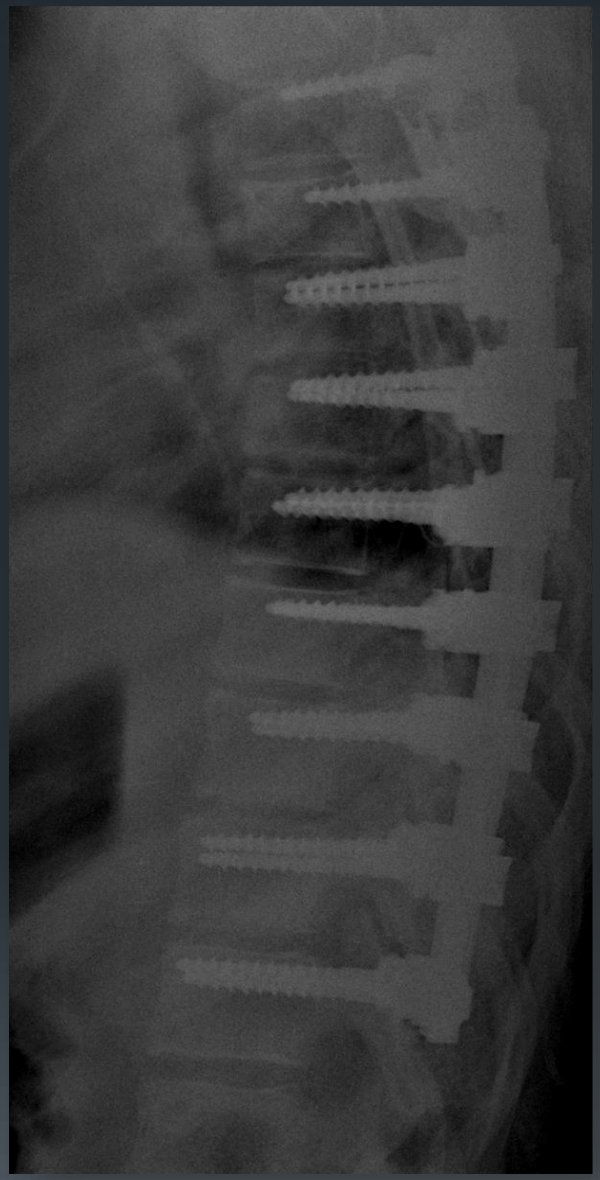
Accuracy results: first 120 pts.

- 1,779 screws in group 'A' precise (98%)
- 30 screws in group 'B' equivocal (1.65%)

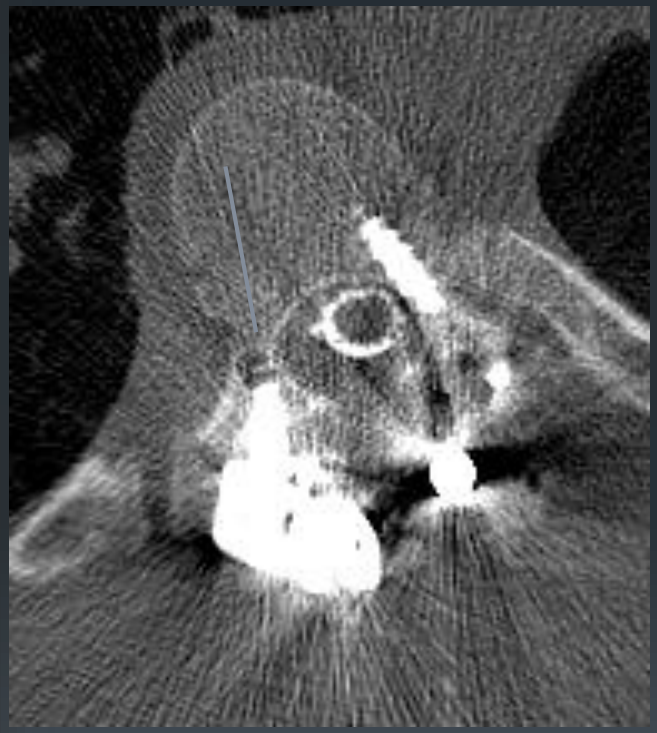
99.65 %

- 6 screws in group 'C' misplaced (0.33%)
  - 2 screws identified as placed outside drill hole; (screw insertion error)
  - all lateral wall penetrations
- no neurological complications; no post-op revisions
- 13 screws placed trans-muscular without direct visualization of drilling site
  - 12/13 graded as 'precise'; 1 partially in the superior vertebral endplate (T4) graded 'equivocal'





“A” - precise



Podium Presentations

- June 2010: Geneva, Switzerland
  - Computer Assisted Radiology and Surgery Meeting
- May 2011: Montreal, Canada
  - Pediatric Orthopedic Society of North America Meeting
- July 2014: Valencia, Spain
  - International Meeting on Advanced Spine Technology
- September 2014: Xi'an, China
  - World Congress of Orthopedics
- March 2015: Las Vegas, Nevada
  - American Academy of Orthopedics
- May 2016: Florence, Italy
  - Italian Scoliosis Society and National Society Spine Surgeons

Are these results reproducible?

- Single center success only….

  - Only my techs could make the robot work

Multicenter AIS study (IMAST 2014)
- AIS clinical **accuracy** -

	Total cases	Total screws placed w/ robot	Avg. # screws with robot	precise screws	% accurate screws	% Misplaced screws
Surgeon 1	120	1815	15.1	1809	99.7%	0.33%
Surgeon 2	7	142	20.3	140	98.6%	1.41%
Surgeon 3	25	324	13.0	324	100.0%	0.00%
Surgeon 4	21	355	16.9	353	99.4%	0.56%
Surgeon 5	50	638	12.8	626	98.1%	1.88%
Total	**223**	**3274**	**14.7**	**3252**	**99.3%**	**0.67%**

Devito, Hedge, Lieberman, Bederman, Woo

Results: instrumentation time

- Average: **4.5 minutes/screw –**

Includes registration, robot mounting and movement, drilling and probing pedicle, screw insertion

  - Varied with surgical technique:
    - drill all pilot holes then place screws (after robot is removed from surgical field)
    - immediate screw placement after each drill

  - Standard deviation: **1.5 minutes/screw**
    - Consistently low, in both techniques

Robotic Accuracy: Most Studies 98-100%

Year	Journal	Author	# of Implants			Accuracy %			Comments
			RO	FH	NAV	RO	FH	NAV	
2015	Spine	Kim	80	80		100	99		RCT, RO MIS, FH open
2012	NuroSrg	Roser	72	40	36	99	97.5	92	RCT, RO MIS, Nav open, FH open
2012	ESJ	Ringel	146	152		85	93		RCT, RO MIS, FH open
2011	ESJ	Kantelhardt	250	286		98.9	96.5		35/55 RO MIS, FH Open
2010	Spine	Devito	3,271 (CT: 646)			98 (98.3)			14 sites, 49% of screws MIS
2012	ESJ	Hu	960			98.9			Deformity + revisions
2014	JTN	Onen	136			98.5			40% MIS
						97.9%			

RCT = Randomized Controlled Trial
RO = Robotic
FH = Free Hand
NAV = Navigation
MIS = Minimally Invasive Surgery

Surgery & Fluoro times in Freehand-open, Freehand-MIS, and Robotic MIS in Short and Long Fusions

2015, TM. Sweeney, et al
Southeastern Spine Center, Florida

266 patients with either short (1-3 levels) or long (>4 levels) fusions

Robotic arm avg. 8 screws per case (all MIS):

-- robot guided surgeries with shortest procedure times, followed by FHO

-- **radiation exposure significantly lower in robot-guided procedures**
- 58-69% lower than FHO
- 55-70% lower than FH-MIS

Prospective Comparative study of Robotic-guidance vs Freehand in MIS spinal fusions

2016, Zahrawi, F, et al.

Prospective, multi-center, comparative study of surgical **complications and revisions**

Results: 143 cases from 4 sites; matched demographics

-- fluoro time FH = 12.5 sec vs. 3.2 sec in robotic group (p<0.001)
-- 2 complications in FH group; both required <u>surgery revision</u> none in robotic arm (p=0.03)

Improved Clinical Efficiency with Robotic Guidance: 10 year Experience in Pediatric Deformity

2016, Devito & Blizzard

Prospective data base collected over 10 years:

-- single surgeon experience **> 500** cases

Comparison previously presented **first 120 cases** (2006-11) to **last 50** consecutive cases (2015-16)

Outcome measures of OR workflow:

-- robot usage (registration to screw insertion time)

-- fluoroscopy usage

-- operating time (skin to skin)

10 year comparison efficiency

Series one (first 120 cases): 85% of 2096 screws executed as planned (1772 screws)
Series two (last 50 cases): 91% 0f 991 screws executed as planned

Total case time reduced by avg. 38 minutes in series two (p=0.003)
- avg. 230 min/ case skin to skin – avg 14.5 screws

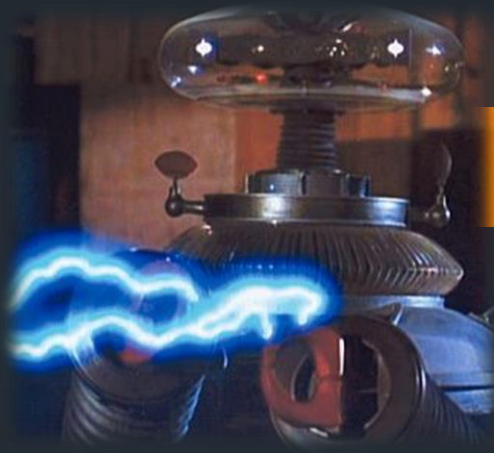
Total robotic usage time (mounting platform, registration, robot movement, drilling) was **reduced by 34 minutes (p<0.001)**

-- from avg. 4.5 min/screw → to **1.9 min/screw (p<0.001)**

Fluoroscopy time between series one and two **reduced by 50%** (36 sec to 18 sec)

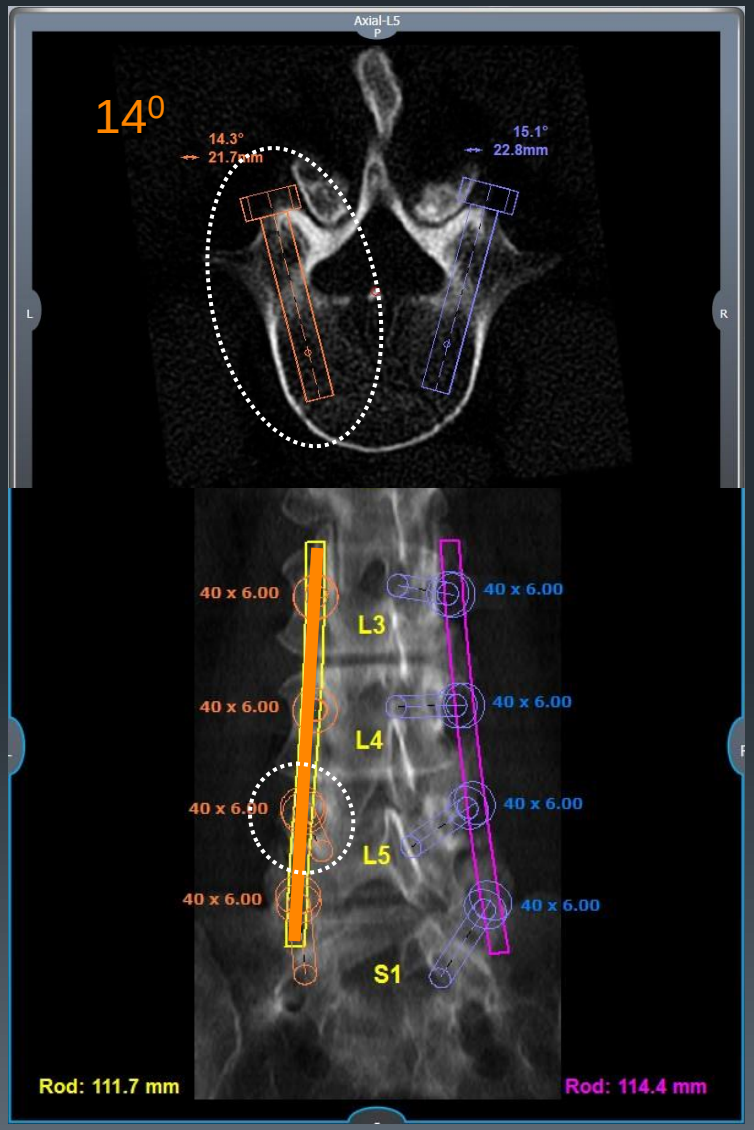
-- current fluoro time = 0.5 sec/screw (p<0.001)
-- includes checking implant position and final spinal balance

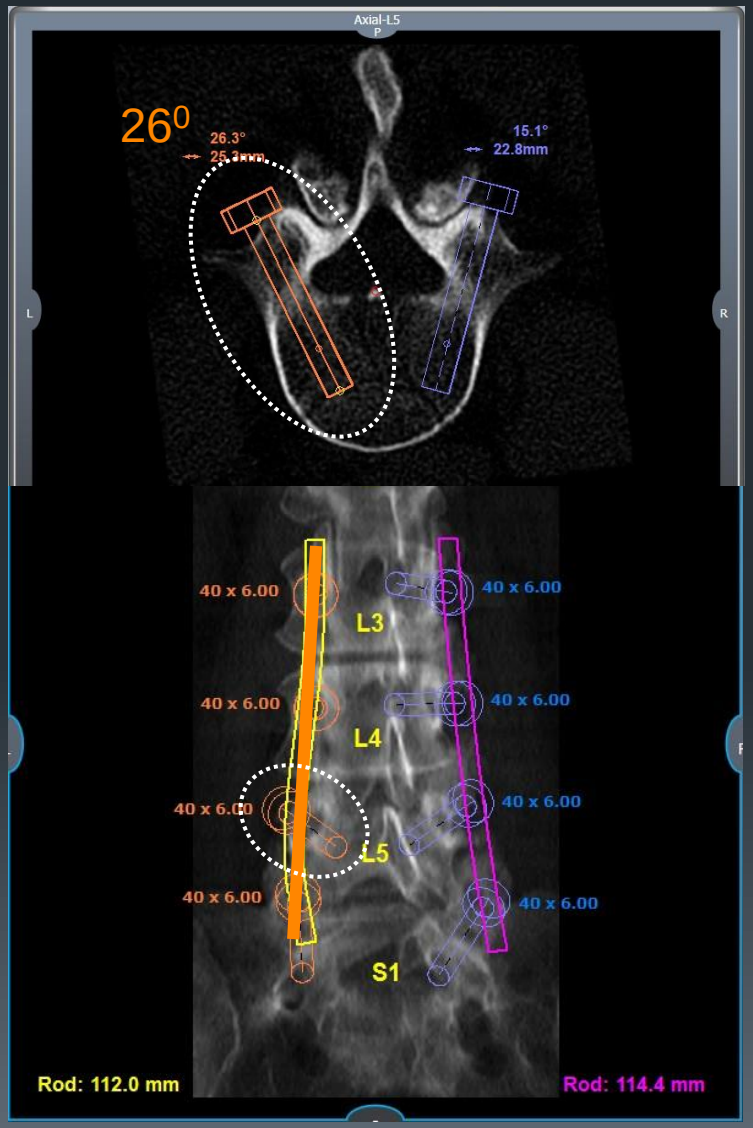
Advantages of robotics



- Improved intra-operative efficiency and accuracy
  - consistent instrumentation times regardless of anatomy
- Minimal direct visualization capability
  - MIS, S2AI trajectories
  - Reduced radiation to the surgical team
  - Less revisions, shorter operative times
- Plan screw cadence for facilitating rod insertion
  - especially relevant for MIS
- Focus on surgical correction rather than implant insertion
  - optimal bone fixation pre-planned
- Recognition of abnormal anatomy before going to OR

Planning screw cadence



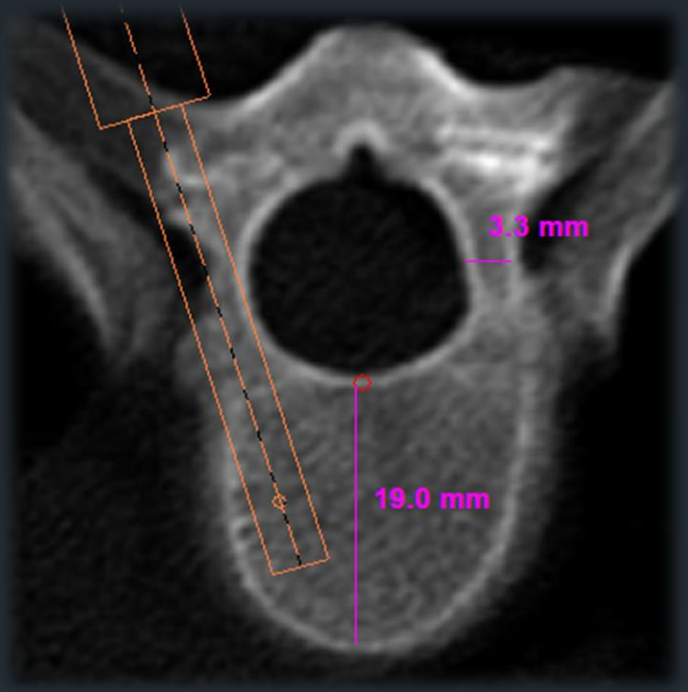


Additional benefits & surprises

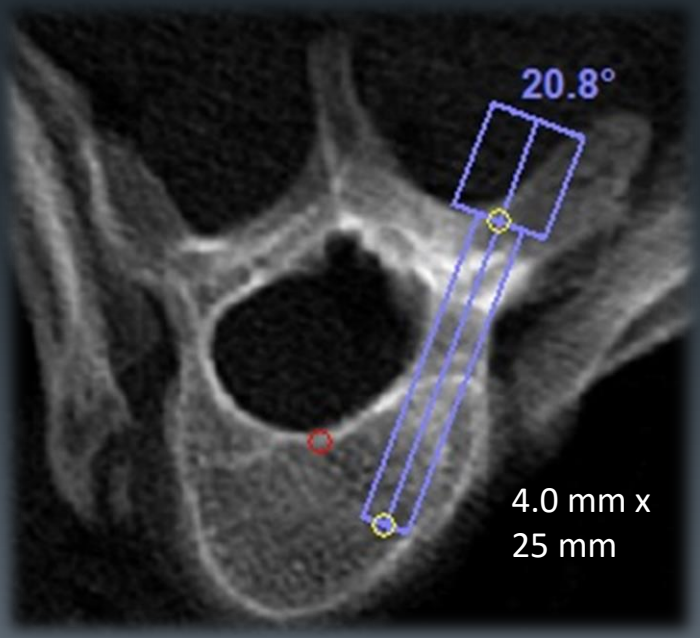
- Uncovering 3-D anatomy of spinal deformity
  - unpredictable, esp. from plain radiographs
  - abnormal pedicle anatomy
  - abnormal vertebral shape
- More prepared for the surgery
  - NAV users never review CT prior to OR
- 3 view CT scan of planned screws
  - enhances safety
  - reinforces understanding 3D anatomy
    - **makes you better at freehand !**

Abnormal anatomy

- **Hypo-plastic pedicles**
  - 33 % vertebra in AIS
    (Sarwahi et al JBJS 2014)
  - Thoracic region more common



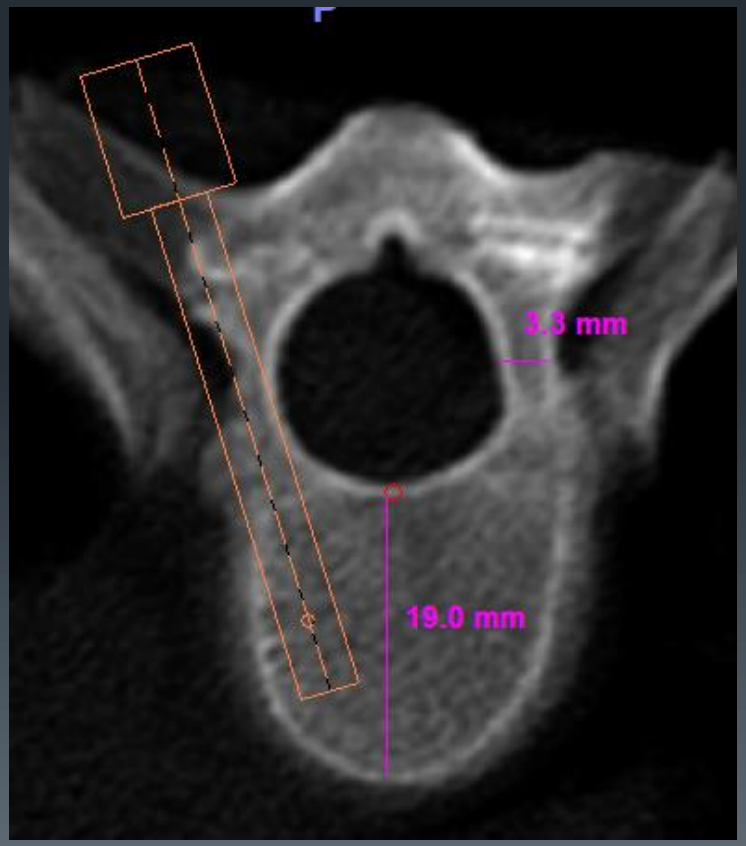
- **Distorted vertebral body**
  - 'windswept'
  - 'V' shaped
  - Small cross sectional area for screw capture

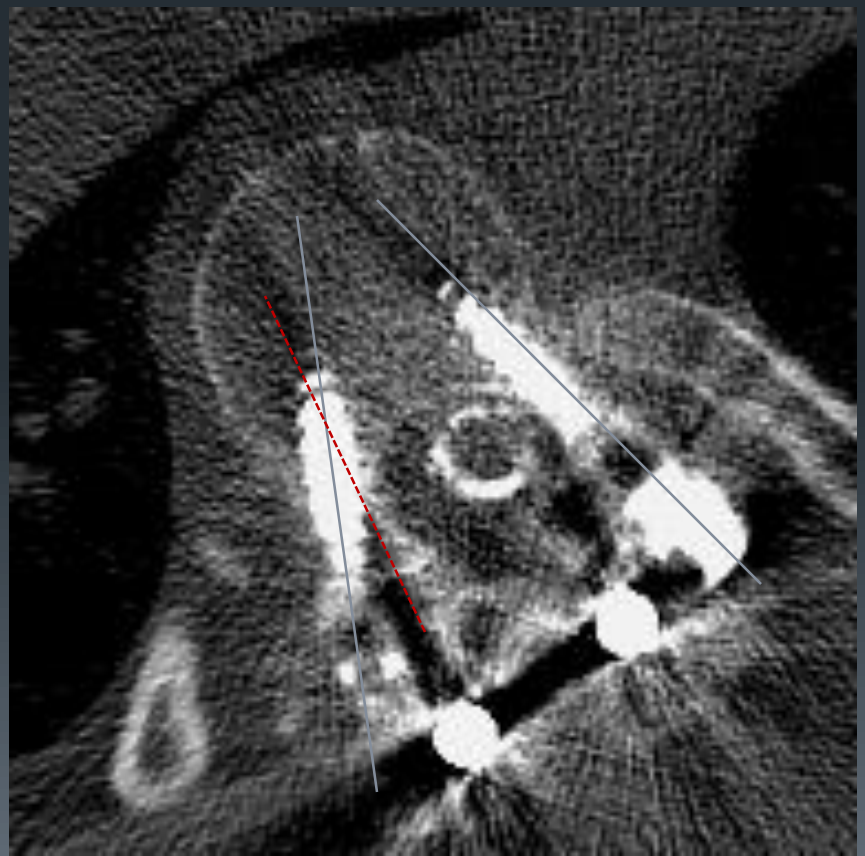


Hypoplastic Pedicles

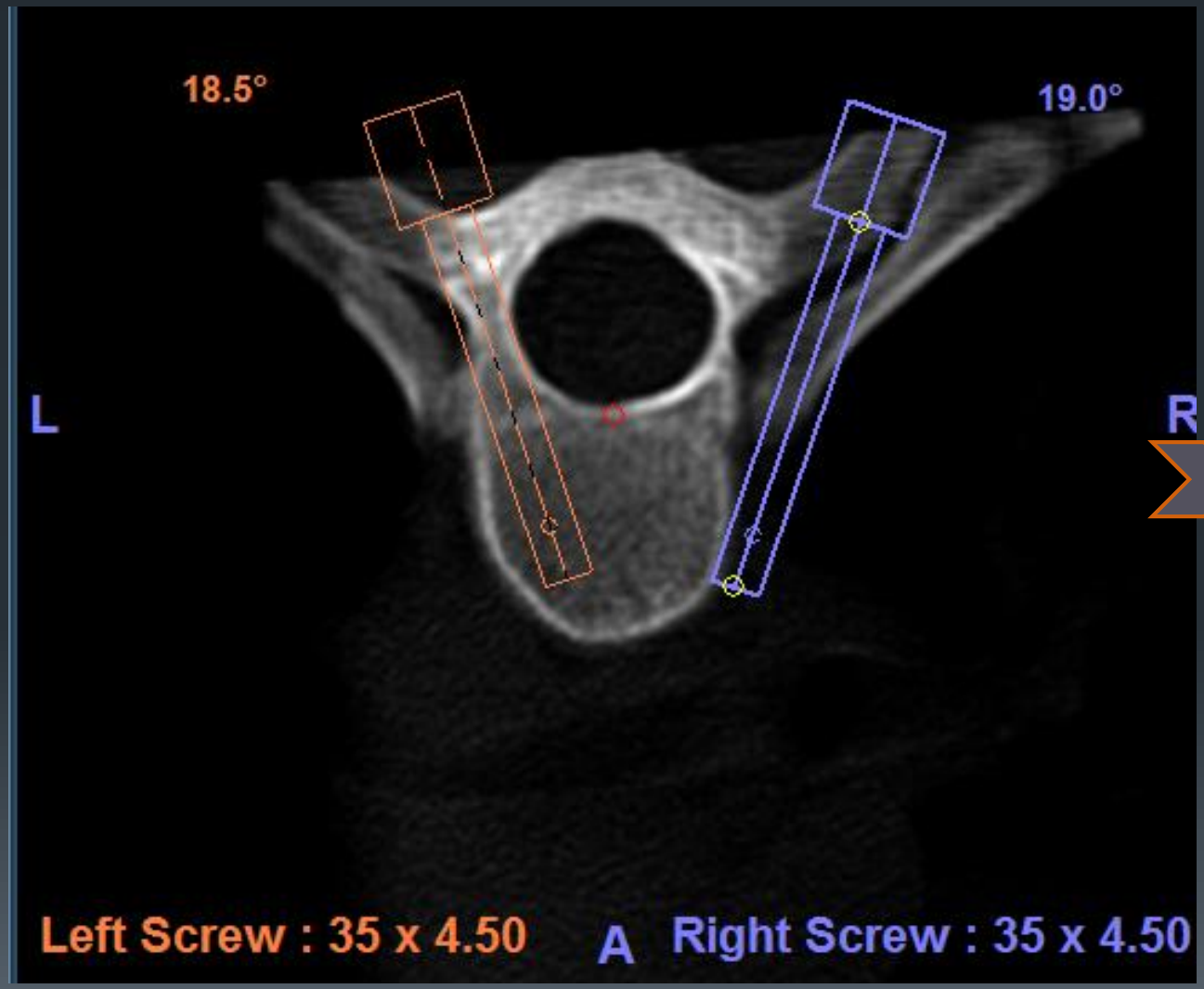
CHOA series:

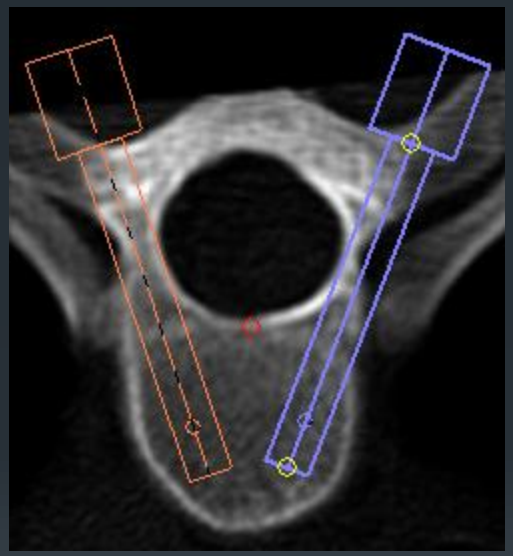
- **486 instrumented pedicles (26%) less than 4 mm**
  -- required no additional time for screw insertion





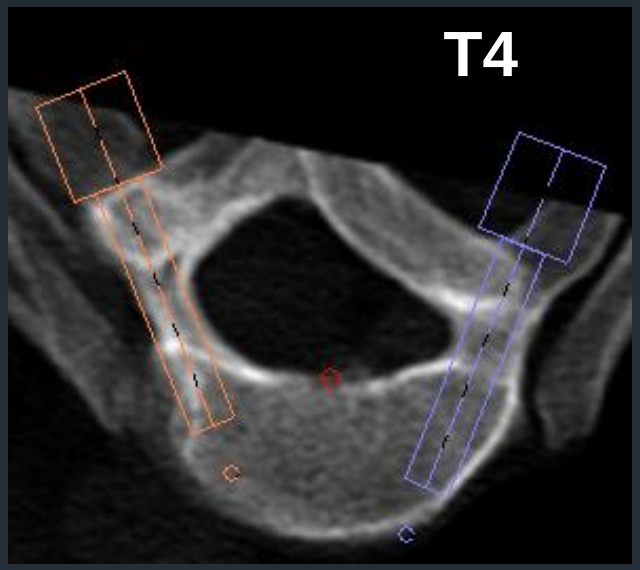
Sclerotic Pedicle – ‘in out in’ strategy



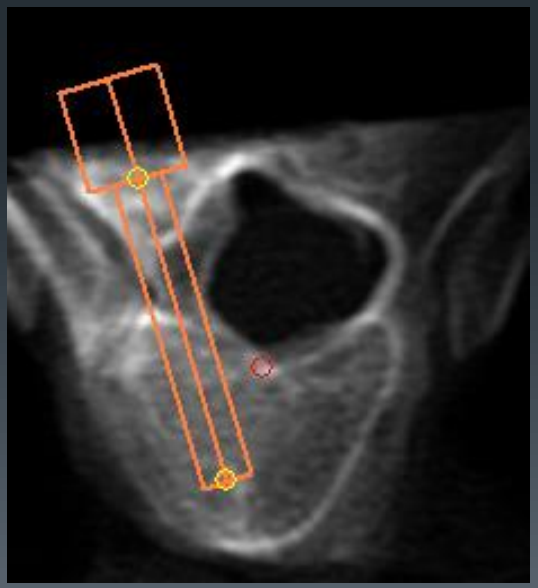


T5

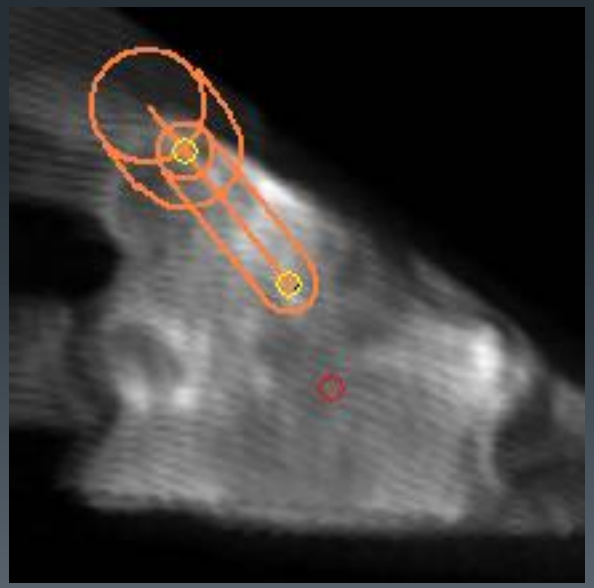
Dysplastic Pedicles



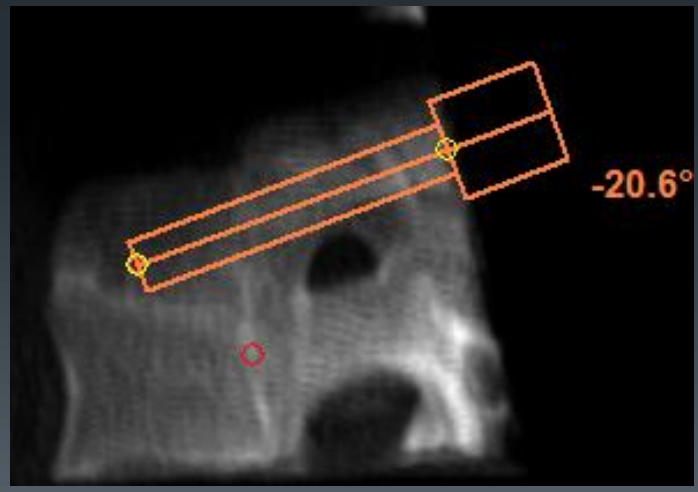
T6



Axial

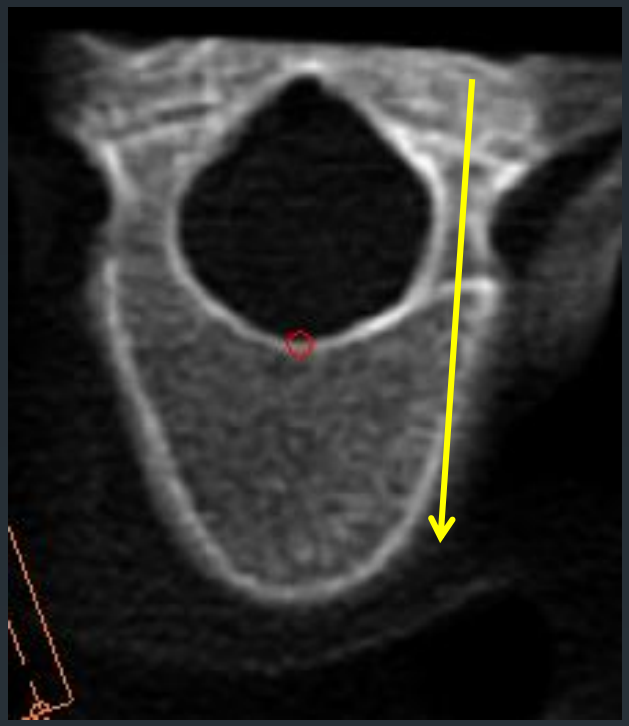


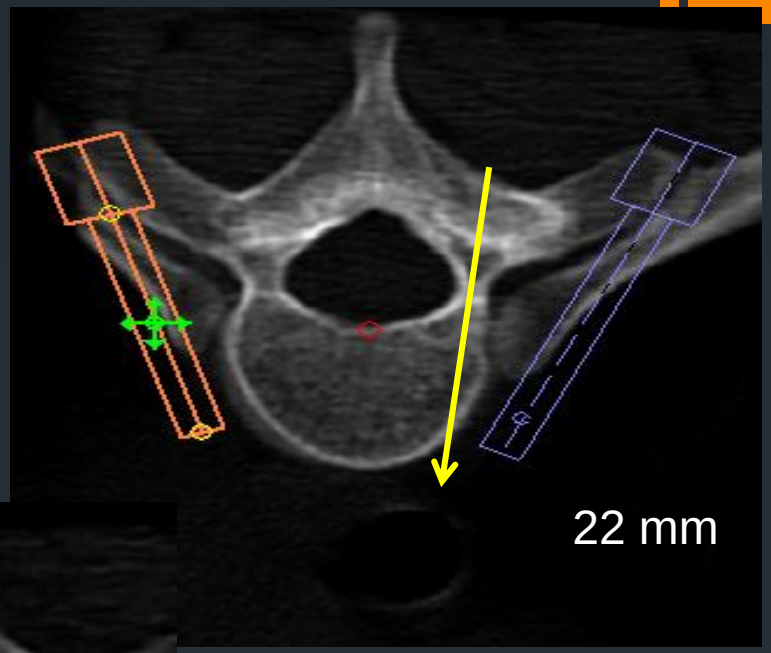
AP

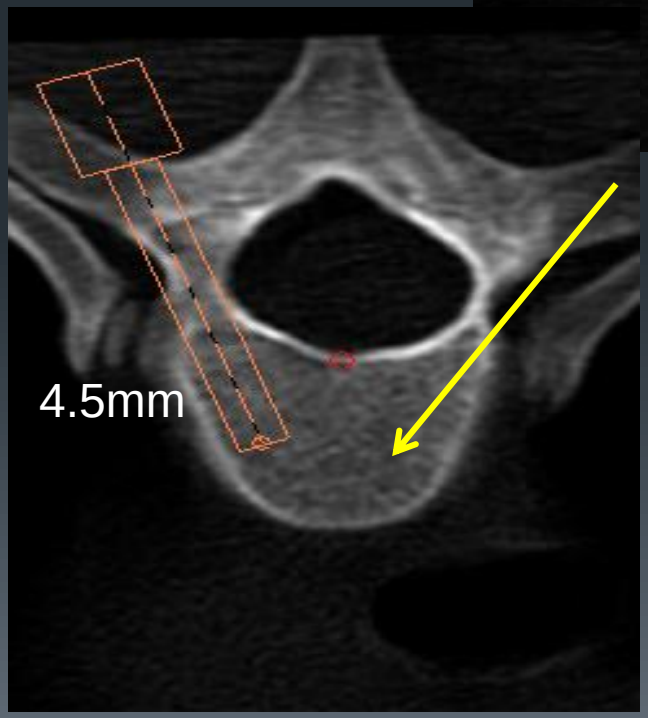


Lateral

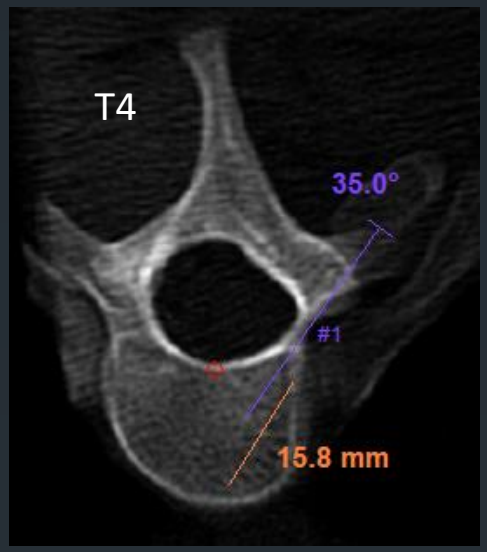
Small or “V” shaped vertebral body

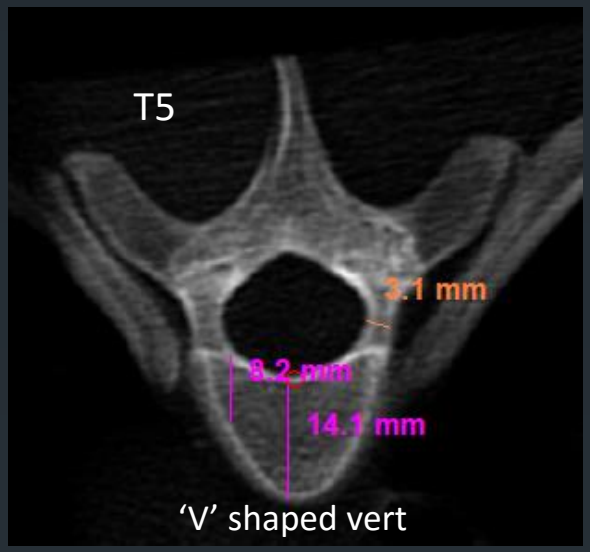


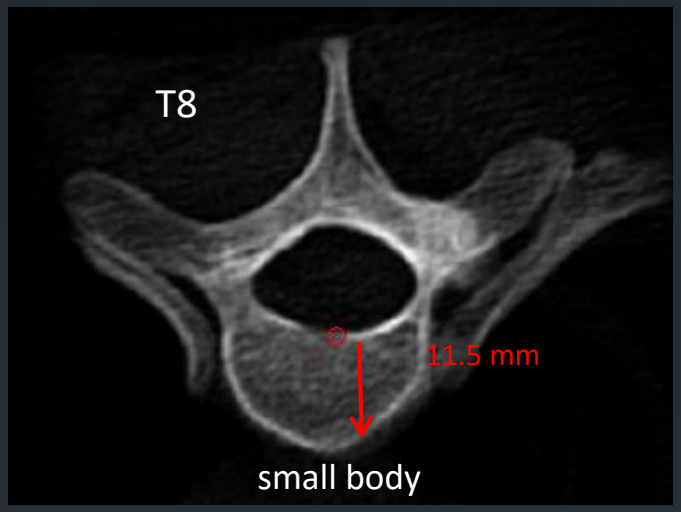


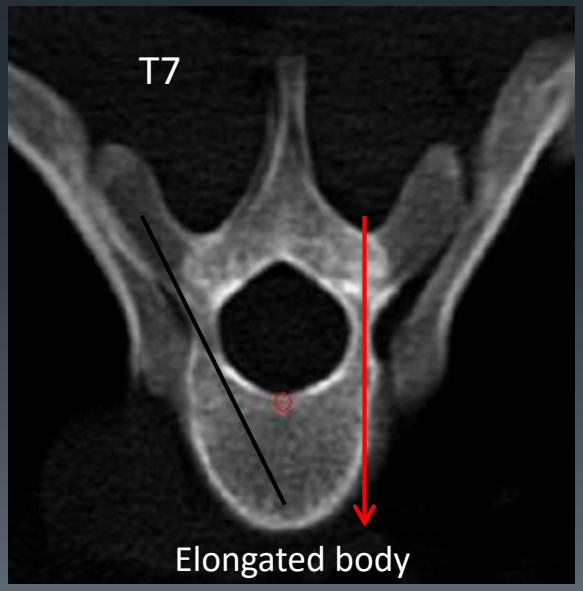


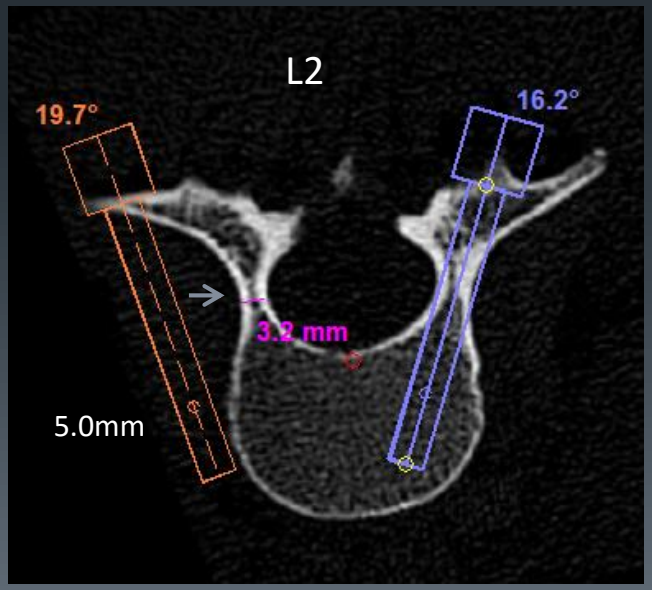
combination hypoplastic pedicle and vertebral body shape











Risks and disadvantages

- **Robot reach** – platform may preclude certain trajectories
  - Intra-operative adjustment usually possible
  - May need additional soft tissue exposure, esp cephalad regions
  - Solution may be Mazor X
- **Attention to docking accuracy**
  - Prep of drill guide placement site to avoid skiving during drilling
  - Meticulous pre op planning
  - No excessive torque applied to drill
  - Complacency
- Registration and robot movement speed
  - Renaissance registration relatively fast – currently better than X ?
  - Arm movement between levels faster with Mazor X

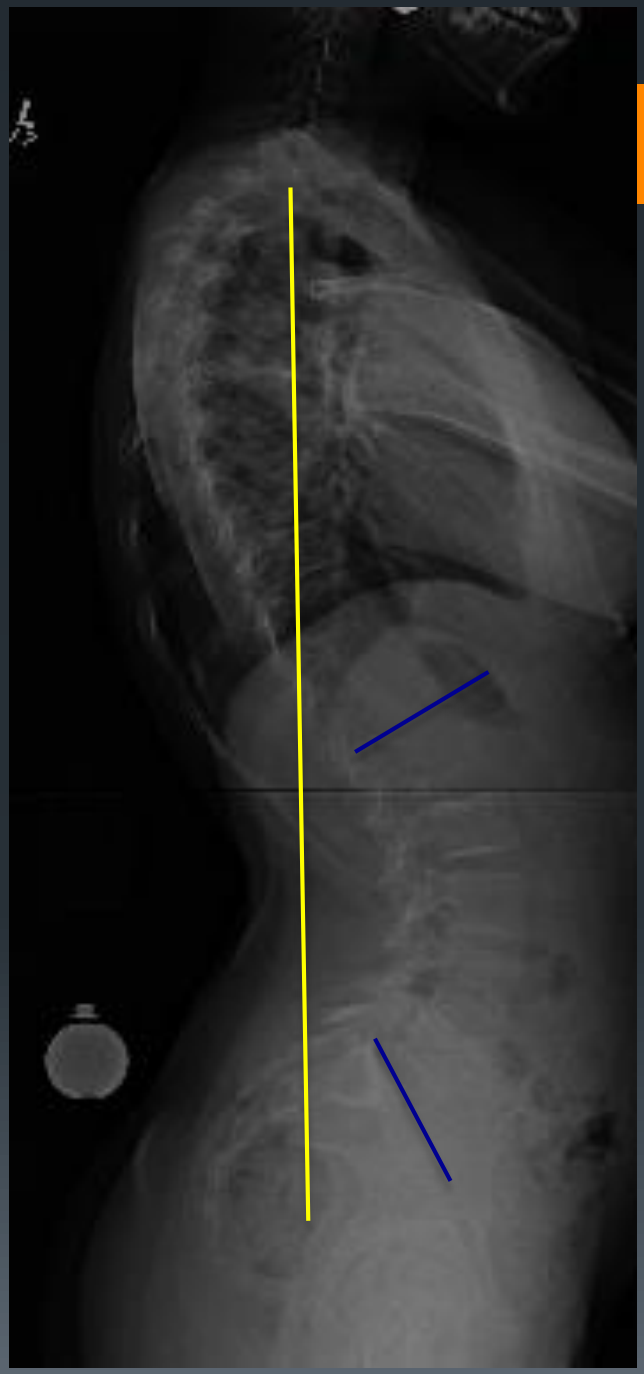
What is the future – where are we going ?

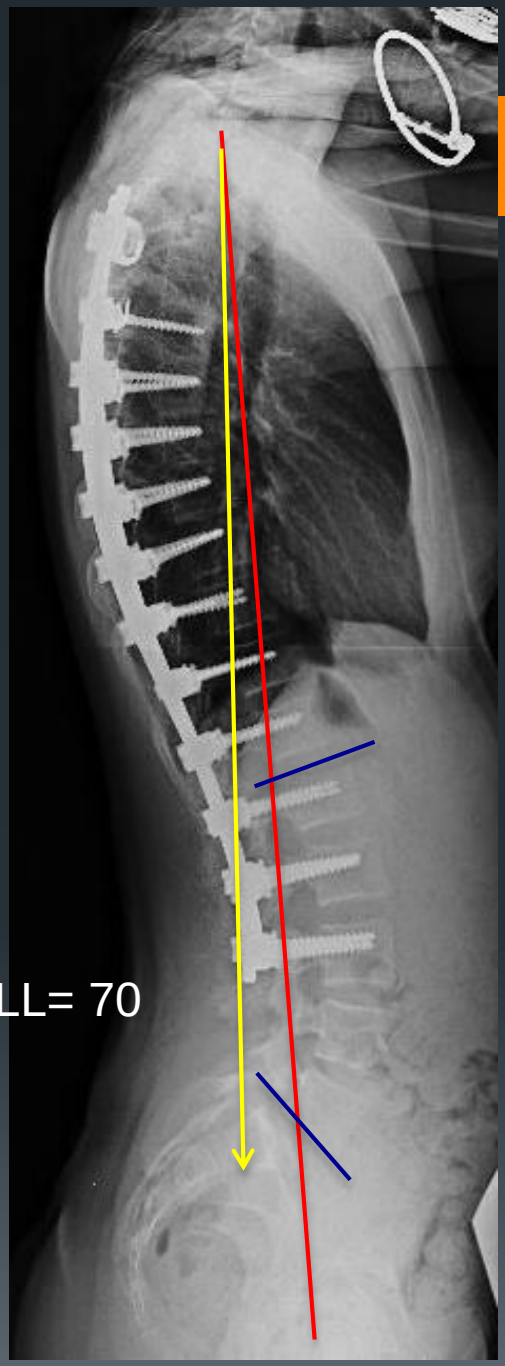
- **Clinical research**
  - Prospective data collection:
    - **Robotic guidance versus freehand (or NAV) – outcomes, abandoned screws**
    - **Implant density and the ability to control sagittal profile**
    - **Identifying critical levels for instrumentation when correcting deformity**
    - **Need for screw EMG testing with robotic guided insertion**

- **Mazor X**
  - Refining work flow for deformity cases
    - better reach, greater range trajectory
  - Evolution to more ‘active’ robotic tools and intervention

Mis-match of
pelvic incidence
and
lumbar lordosis

PI = 71°
LL = 87°
Δ = 16°




LL= 70

All pedicles hypoplastic, < 4mm

Small vertebral bodies:
- horizontal pedicle entry angle

Conclusions

- High feasibility and performance in executing surgical plan
  - Low number of abandoned screws
- Implant insertions:
  - Accurate at a high level – **> 99%**
  - No nerve deficits
  - Insertion times consistent across all levels of the spine, **multiple users**
- Value of pre-op planning emphasized – **greater surgeon preparedness**
  - Ability to identify abnormal anatomy
  - Ability to design ideal screw size and trajectory
- Reduced radiation exposure, especially intra-operative
  - New CT protocols promising for further reducing rad exposure

Conclusions

Great patient acceptance

technology designed for safety

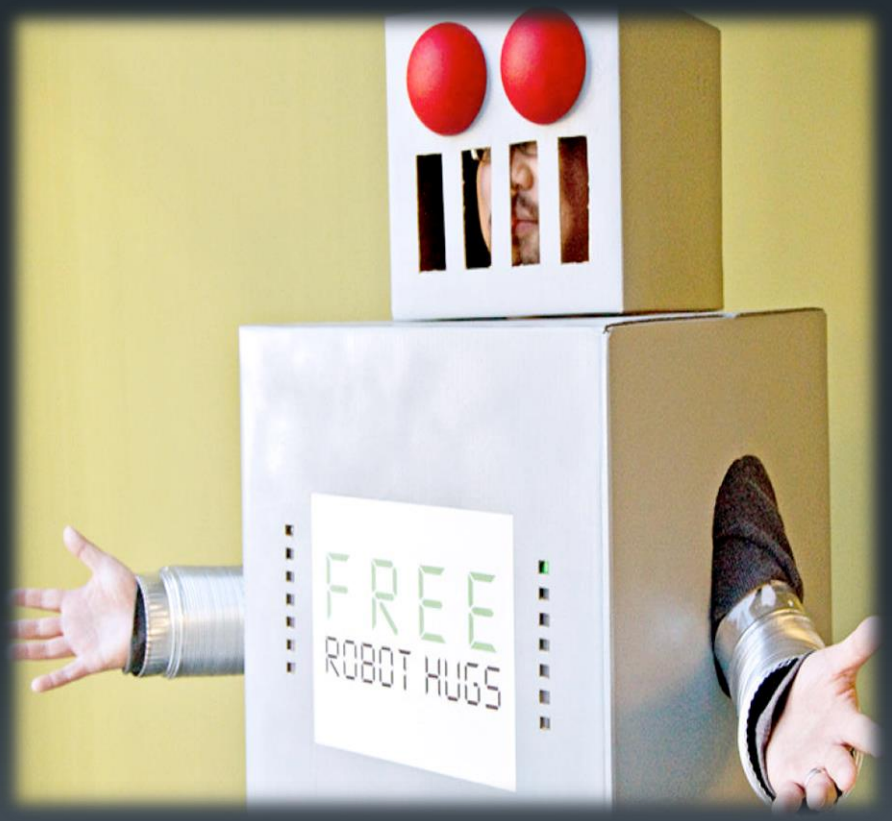
Growth of spine practice

Clinical efficiency

consistent OR times

less time spent on difficult screw insertions

less revisions for misplaced screws



It has made me a better spine surgeon – unsettling that I free-handed so many cases……

Robotic assisted spine surgery has passed the inflection point of clinical effectiveness

- Value = clinical benefit / cost
- Define cost not in hosp $$, but as it relates to you the surgeon:
  - Increased accuracy → better outcomes → decreased liability
  - Less revisions
  - Efficiency/time ratio favorable
  - Radiation exposure ↓
  - Less fatigue

Thank you