Overview of ISSG and Health Impact of Adult Spinal Deformity

Shay Bess, MD

News from the Frontlines of Adult Spinal Deformity Research and Treatment

VuMedi Webinar

August 2013

ISSG INTERNATIONAL SPINE STUDY GROUP

Rocky Mountain Hospital for Children | Rocky Mountain Hospital For Children at P/SL *A new generation of care*

Disclosures Shay Bess

- Consulting= Depuy/Synthes, Medtronic, Allosource, K2M, Alphatec
- Royalties= Pioneer Spine, K2M
- Research support= Depuy/Synthes, Medtronic, K2M
- Scientific advisory board= Allosource

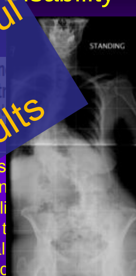
Adult Spinal Deformity and Disability

- Traditional teaching= scoliosis is not painful
- "Supporting evidence"
  - Weinstein SL, et al. JAMA 2003
  - Weinstein SL. JBJS 2000
- Results
  - LIS =more pain and cosmetic vs controls
  - LIS 68%= little or moderate pain (similar to controls)
  - No effect on function, marital status

Health an... With Untr... ...osis

A 50-Year N...

"It is ess... commun... the publi... is likely t... physical... than bac... concerns."



ASD is not "really" painful

Treatment is unnecessary in adults

Adult Spinal Deformity and Disability

- Problems Weinstein Studies

1. No standardized HRQOL
   – Modified pain, depression, function and cosmesis scores
2. No sagittal analysis
   – All patients= PA only
   – Fundamental ASD evaluation
3. Sagittal spinopelvic malalignment
   – Foundation pain and disability spinal deformity
   – Primary reason for not diagnosing pain ASD

International Spine Study Group

- ASD research needs:
  – Standardized clinical/radiographic evaluation
  – HRQOL correlations
  – Best practice guidelines
    • Clinical, economic, complications
- ISSG: Multi-center research group
  – 13 sites
  – Evaluation & treatment ASD
  – Radiographic, psychological, HRQOL
  – Cost effectiveness
  – Heath impact vs. disease states
  – Preoperative planning
  – Complications

Site	Members
OHSC	Hart
UC Davis	Gupta, Klineberg
UCSF	Ames, Deviren, Mummaneni
San Diego	Akbarnia, Mundis, Eastlack
Colorado	Bess. Line
Baylor	Hostin, O'Brien, McCarthy
Kansas	Burton
Johns Hopkins	Kebaish
Washington Univ	Buchowski
HSS	Boachie, Kim
NYU/HJD	Lafage, Schwab
Virginia	Shaffrey, Smith

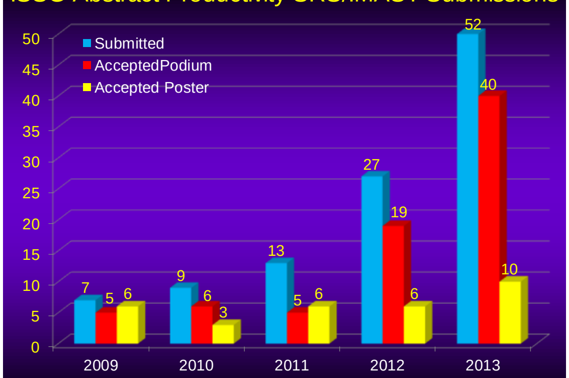
ISSG Structure

- Independent private foundation (ISSGF 501 3c formed 2010)
- Online database (initiated 2009)
  – Host site data entry; central data QA
- Centralized radiographic measures (initiated 2009)
  – Upload to FTP server (NYU site); measurements SpineView software
- Personnel
  – Central coordinator
  – Accountants and legal
  – Health economists (JHU faculty and Baylor)

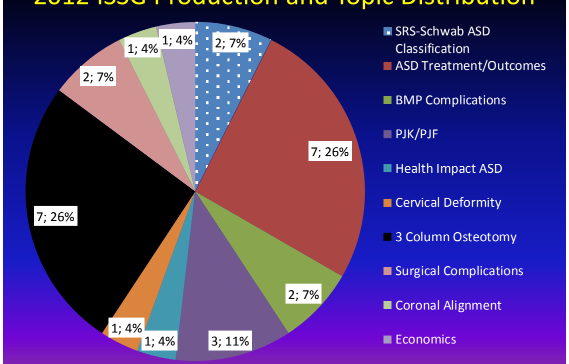
ISSG Projects

1. Prospective Operative vs. NonOp for ASD
   - Consecutive enrollment ASD (scoliosis ≥20°, SVA≥5cm, PT≥25°, or TK> 60°)
   - Total =906; OP=415; NON=491
2. Three Column Osteotomy Database (3CO)
   - Total =776 (data collection on going)
   - Complete radiographic data=572
3. Proximal Junctional Failure (PJF); initiated 8/2012
   - Retrospective analysis PJF in ASD
   - Definition, incidence, risk factors, treatment
4. Prospective Cervical Deformity (PCD); initiated 1/1/2013
   - Operative treatment adult PCD
5. Low grade adult spondylolisthesis; funding approved 2/2013
6. Cost effectiveness OP vs. NON for ASD; funding pending
7. Root cause analysis for success and failure of ASD surgery; pending

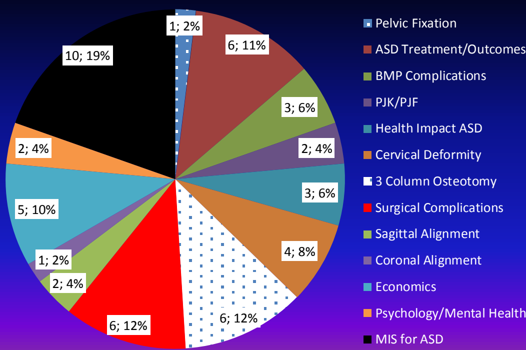
ISSG Abstract Productivity SRS/IMAST Submissions



2012 ISSG Production and Topic Distribution



2013 ISSG Production and Topic Distribution



Health Impact Comparison of Different Disease States and Population Norms to Adult Spinal Deformity (ASD): A Call for Medical Attention

Kai-Ming Fu MD, Shay Bess MD, Frank Schwab MD, Christopher Shaffrey MD, Virgine Lafage PhD, Justin Smith MD, Christopher Ames MD, Oheneba Boachie-Adjei MD, Douglas Burton MD, Robert Hart MD, Eric Klineberg MD, Richard Hostin MD, Gregory Mundis MD, Praveen Mummaneni MD, and the International Spine Study Group

North American Spine Society 2012 (Best Paper Nominee)
Scoliosis Research Socitey 2012
American Academy of Orthopaedic Surgeons 2013
American Academy of Neurosurgery 2012
AANS/CNS Joint Section 2013

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Background Information

- SF-36 for ASD
  - Little data comparing disease impact ASD vs. other disease states
- Study Purpose
  - Use SF-36 baseline values
  - Consecutive cohort ASD patients
  - No prior spine surgery
  - Compare ASD SF-36 values
    - United States general population
    - United States generational norms
    - United States disease specific norms
  - Compare disease impact using MCID values

Materials and Methods

- Data collection
  - Demographic, radiographic, HRQOL
- ASD SF-36
  - Physical component score (PCS)
  - Mental component score (MCS)
  - Compared to United States (US)
    - Total population norms
    - Age generational norms
    - Disease specific norms
  - Norm based scoring (NBS)
  - MCID values (cross-sectional)
    - PCS= 3 NBS points
    - MCS= 3 NBS points

Results: Total

- ASD Demographic & Radiographic
  - N=497
  - Age 50.4 years
  - Scoliosis= 45.3°
  - PT= 18.8°
  - SVA= 19.9mm
- ASD vs. U.S. total population
  - PCS=-9 NBS (3 MCID)
  - MCS= similar
- ASD vs. U.S. generational norms: PCS
  - Minimum 2 MCID lower
  - <25th percentile
  - All generations except 18-24yrs; (-2.2 NBS)
  - More rapid decline than U.S. general

	ASD (n=497)			Mean values (SD)		
Generational Age Groups (n=total ASD patients)	ASD PCS; NBS value (SD)	US Population PCS; NBS value	PCS Difference (percentile US general population)	ASD MCS; NBS value (SD)	US Population MCS; NBS value	MCS difference
18-24 years (n=42)	51.3 (8)	53.5	-2.2 (<50th)	48.2 (10.5)	46.1	+2.2
25-34 years (n=75)	46.9 (9.2)	53.6	-6.7 (<25th)	50.8 (9.6)	49.1	+1.7
35-44 years (n=52)	42.3 (9.5)	52.3	-10 (<25th)	49.7 (9.0)	49.1	+0.6
45-54 years (n=88)	41.9 (10.5)	49.7	-7.8 (<25th)	50.4 (10.9)	50.6	-0.2
55-64 years (n=138)	38.7 (10.6)	47.4	-8.7 (<25th)	47.1 (13.1)	51.6	-4.5
65-74 years (n=73)	33.6 (10.3)	44.7	-11.1 (<25th)	50.9 (11.7)	52.8	-1.9
≥75 years (n=29)	31.7 (9.5)	39.9	-8.2 (<25th)	52.8 (8.5)	50.2	+2.6
Total population (n=497)	40.9 (11.2)	50	-9.1 (<25th)	49.4 (11.3)	50	-0.6

Leg Pain; NRS	2.63 (3.1)

Results: ASD No Other Comorbidities

- ASD No Other Comorbidities vs. U.S. Total and Generational Norms
- PCS
  - Minimum one MCID lower U.S. norms
  - <25th percentile
  - ASD generations (except 18-24 yr)
  - More rapid decline than U.S. general
- MCS
  - Similar

Generational Age Groups (n=total ASD patients)	ASD PCS; NBS value (SD)	US General Population PCS; NBS value	PCS Difference (percentile US general population)	ASD MCS: NBS value (SD)	US General Population MCS; NBS value
18-24 years (n=30)	52.7 (7.3)	53.5	-0.8 (<50th)	48.8 (10.7)	46.1
25-34 years (n=58)	46.8 (9.6)	53.6	-6.5 (<25th)	51.2 (8.9)	49.1
35-44 years (n=34)	43.2 (10.3)	52.3	-9.1 (<25th)	50.2 (9.6)	49.1
45-54 years (n=47)	43.2 (10.8)	49.7	-6.5 (<25th)	49.9 (11.3)	50.6
55-64 years (n=57)	42.4 (9.7)	47.4	-5.0 (<25th)	48.9 (11.4)	51.6
65-74 years (n=14)	35.8 (11.1)	44.7	-8.9 (<25th)	51.9 (12.2)	52.8
≥75 years (n=6)	36.8 (10.8)	39.9	-3.1 (<25th)	51.4 (9.3)	50.2
Total population (n=246)	44.4 (10.5)	50	-5.6 (<25th)	50.2 (10.5)	50

Results: ASD vs. U.S. Disease Norms

- ASD vs. U.S Healthy and Disease Norms
- PCS
  - Healthy US<14.5 NBS (4 MCID)
  - Back pain/Sciatica <4.8 NBS (one MCID)
  - Hypertension<3.1 NBS (one MCID)
  - Similar
    - Cancer
    - Diabetes
    - Heart disease
    - Limited use arms or legs
    - Lung disease

Disease State	PCS; mean NBS points	MCS; mean NBS points
US Total Population	50	49.9
US Healthy Population	55.4	52.9
ASD	40.9	49.4
Back Pain	45.7	47.6
Cancer	40.9	47.6
Depression	45.4	36.3
Diabetes	41.1	47.8
Heart Disease	38.9	48.3
Hypertension	44.0	49.7
Limited Use Arms Legs	39.0	43.0
Lung Disease	38.3	45.6

Disease State Correlates for Type and Severity of Adult Spinal Deformity; Assessment Guidelines for Health Care Providers

Shay Bess, Kai-Ming Fu, Virginie Lafage, Frank Schwab, Christopher Shaffrey, Christopher Ames, Robert Hart, Eric Klineberg, Gregory Mundis, Richard Hostin, Douglas Burton, Munish Gupta, Oheneba Boachie-Adjei, Justin Smith, and the International Spine Study Group

20th International Meeting on Advanced Spine Technologies Annual Meeting

Vancouver, Canada
July 2013

IMAST 20th International Meeting on Advanced Spine Technologies

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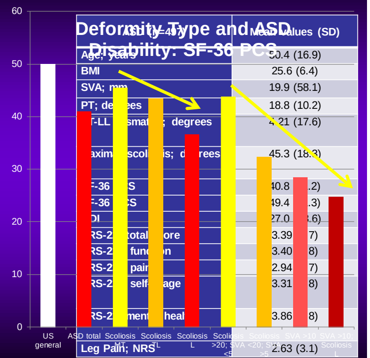
Purpose, Materials and Methods

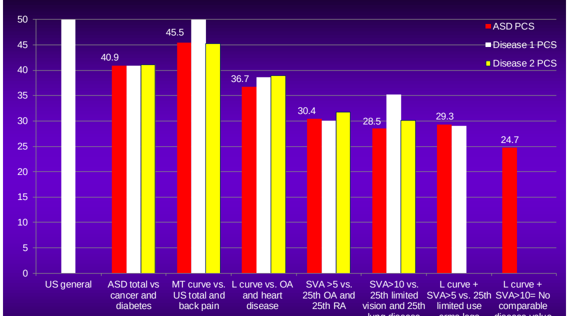
- Study Purpose
  - Compare types/severity ASD
  - Other disease states
- Materials and Methods
  - Consecutive cohort ASD patients
  - No prior surgery
  - ISSG prospective, multi-center database
  - ASD organized
    - Sagittal vs. coronal deformity
    - Deformity severity
  - ASD baseline SF-36 compared
    - United States general population
    - United States disease specific norms
  - Disease impact compared using MCID values

Results: ASD Deformity Type and Disability

- ASD Demographic
  - N=497
  - Age 50.4 years
  - Scoliosis= 45.3°
  - PT= 18.8°
  - SVA= 19.9mm
- ASD PCS
- PCS worsens
  - Curve location
  - Sagittal malalignment
- Multivariate analysis worsening PCS
  - PI-LL (R=-0.44)
  - SVA (R=-0.40)
  - PT (R=-0.38)



Results: ASD Type, Severity and Disease Correlates



ASD Deformity Type:
- Scoliosis Thoracic=2 MCID below General Population
- Scoliosis Lumbar =5 MCID below General Population
- L curve + Severe SSM; SVA>10=PCS lower ANY RECORDED VALUE!!

Conclusions and References

- ASD worsening impact
  - Deformity location
  - Deformity type
  - Deformity severity
- ASD vs. other disease states
  - Greater impact more recognized diseases
- Future work
  - Dissemination: medical community & Federal funding sources
  - Cost effectiveness ASD vs. other disease states
- References

  - Schwab F, Dubey A, Pagala M, et al. Adult scoliosis: a health assessment analysis by SF-36. Spine 2003;28:602-6.
  - Weinstein SL, Dolan LA, Spratt KF, et al. Health and function of patients with untreated idiopathic scoliosis: a 50-year natural history study. Jama 2003;289:559-67.


Thank You
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Proximal Junctional Failure: What is it? Can it be prevented? Novel Approach with VEPTR

Robert Hart, MD
OHSU Orthopaedics
Portland OR

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Conflicts

- Consultant Depuy Spine, Medtronic
- Royalties Seaspine, Depuy
- Stockholder SpineConnect
- Research/Fellowship Support Depuy, Medtronic, Synthes, OREF, MRF, ISSG

Proximal Junctional Failure =

Post-operative Fracture and/or Soft Tissue Disruption at Upper Instrumented or Next Adjacent Segment Following Long Instrumented Fusion

"Topping Off Syndrome"

Proximal Junctional Fracture

Fracture above all Pedicle Screw Construct (FPSC)

Proximal Junctional Acute Collapse

Distinct from "Proximal Junctional Kyphosis"

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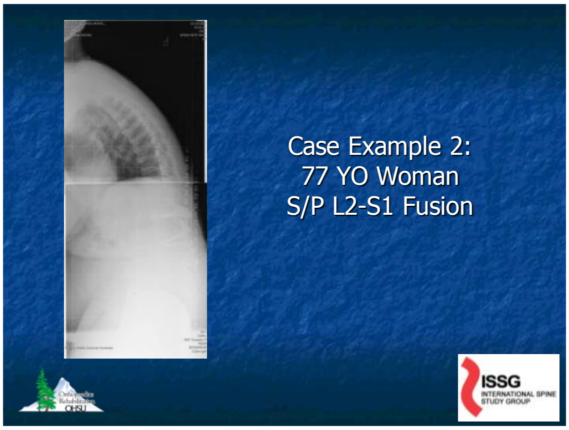
Increasingly Recognized and Described Following Long Lumbar Spine Fusions

- Etebar and Cahill, J Neurosurg, 90:163-9, 1999
- Dewald and Stanley, Spine, 31:S144-51, 2006
- Hart et al., TSJ, 8:875-81, 2008
- Kim et al., Spine, 32:2653-61, 2007
- O' Leary et al., Spine, 34:2134-9, 2009
- Watanabe et al., Spine, 35:138-45, 2010

Case Example 1:
70 YO Woman
1 Level TLIF

2 Year Follow-up
Fracture T10 (UIV)
"Reciprocal Change"


Case Example 2:
77 YO Woman
S/P L2-S1 Fusion
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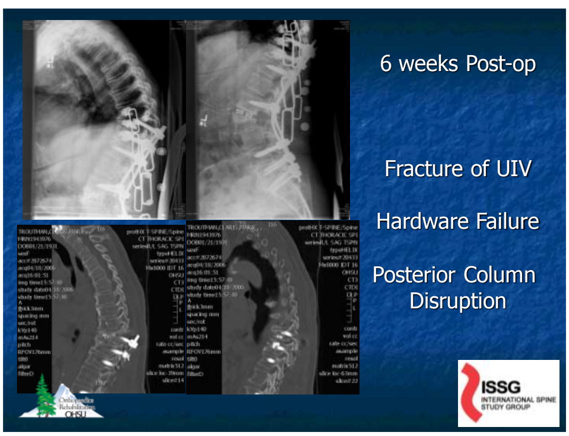
6 weeks Post-op
Fracture of UIV
Hardware Failure
Posterior Column Disruption
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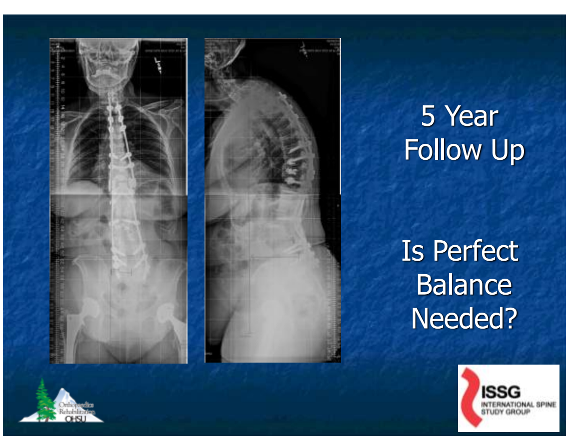
5 Year Follow Up
Is Perfect Balance Needed?
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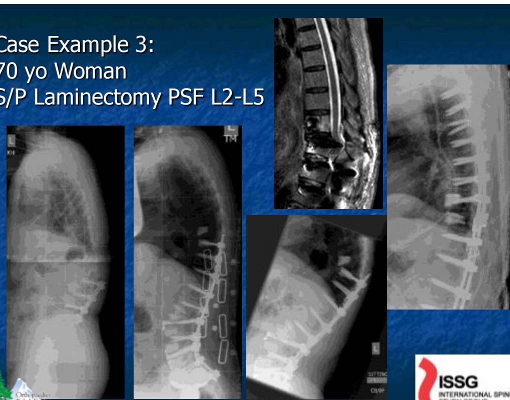
Case Example 3:
70 yo Woman
S/P Laminectomy PSF L2-L5



Risk Factors (Hart/ISSG, IMAST, 2012)

- Age
- Preop TK for all comparisons
- Pre-op SVA and PT for UT
- Pre-op LL, PI-LL, and SS for TL
- Use of PSO for UT
- Change in LL and PI-LL for TL
- Significant Increased Rate of Revision

Potential Preventive Techniques

- Vertebral Augmentation
- Proximal Hooks
- Moving Junction Cranial
- "Tuning" Correction
- "Laying In" Rods to Upper Screws
- Limit Proximal Dissection

Vertebral Augmentation

72 YO Woman
Short Stature
Multi-focal DJD
S/P Laminectomy
Pain Pump

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Vertebral Augmentation

S/P T10-Pelvis

Screw Failure/Fracture
Despite Kyphoplasty

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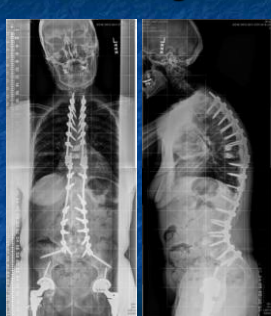
Vertebral Augmentation



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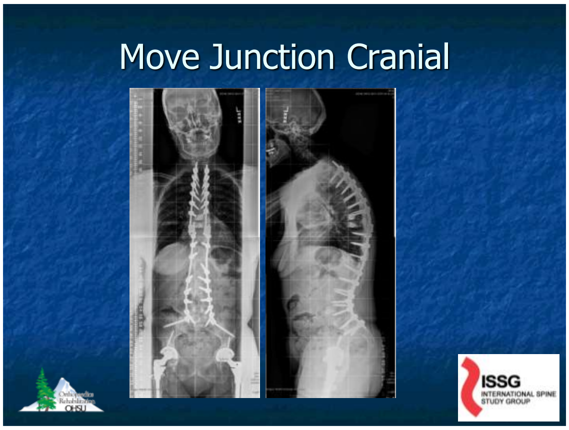
Move Junction Cranial
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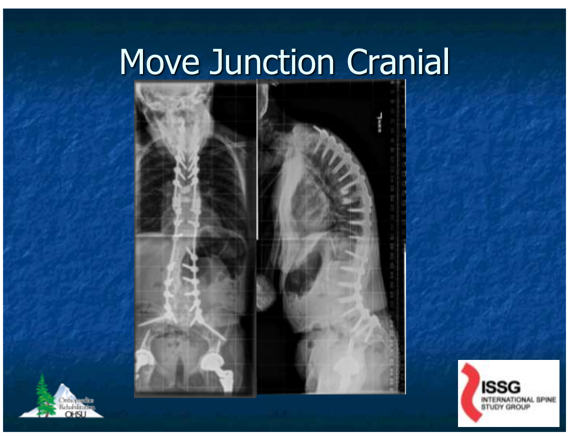
Move Junction Cranial
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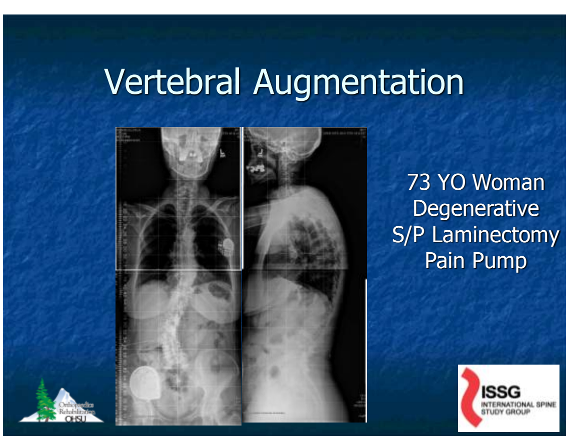
Vertebral Augmentation
73 YO Woman
Degenerative
S/P Laminectomy
Pain Pump
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Vertebral Augmentation

Vertebral Augmentation

DJD at
Proximal Disk
2 Years
Post-op

Proximal Hooks

Proximal Hooks

Summary – Vertebral Augmentation

- Reduces Incidence But Not to Zero
- Avoids Midline Dissection
- May Accelerate Degenerative Disease
- Cost
- Some Fuss in OR

Summary-Proximal Hooks

- No Evidence to Support Reduced Incidence
- Mechanically Questionable
- Doesn't Avoid Proximal Dissection
- Is Simple to Include

Summary- Move Junction Cranial

- No Evidence to Support Reduced Incidence
- Upper Thoracic Failures May be Worse
- Significantly More Surgery
- Doesn't Avoid Midline Dissection

"Tuning" Correction

- ISSG Data Shows Greater PI-LL Mismatch for TL Junction PJF Patients
- Overcorrection May Also Be Harmful
- Clearly Important Surgical Goal But May Not Always Be Attainable

"Laying In" Proximal Rod

- Makes Good Mechanical Sense
- Easy To Do
- Doesn't Reduce Proximal Dissection
- Data Lacking

Limiting Proximal Dissection

- Makes Good Biologic Sense
- Doesn't Change Mechanical Effects
- Some Fuss in OR
- Data to Support Pending

VEPTR Device

Indications
The device is indicated for the treatment of thoracic insufficiency syndrome (TIS) in skeletally immature patients. TIS is defined as the inability of the thorax to support normal respiration or lung growth. For the purpose of identifying potential TIS patients, the categories in which TIS patients fall are as follows:
– Flail chest syndrome
– Constrictive chest wall syndrome, including
– Rib fusion and scoliosis
– Hypoplastic thorax syndrome, including
– Jeune's syndrome
– Achondroplasia
– Jarcho-Levin syndrome
– Ellis van Creveld syndrome
– Progressive scoliosis of congenital or neurogenic origin without rib anomaly

Proximal Rib Fixation with VEPTR

- Reduces Proximal Dissection – Good Biological Sense
- Extends Moment Arm Lateral – Good Mechanical Sense
- Allows Other Surgical Techniques
- Some OR Fuss

VEPTR Device - Technique

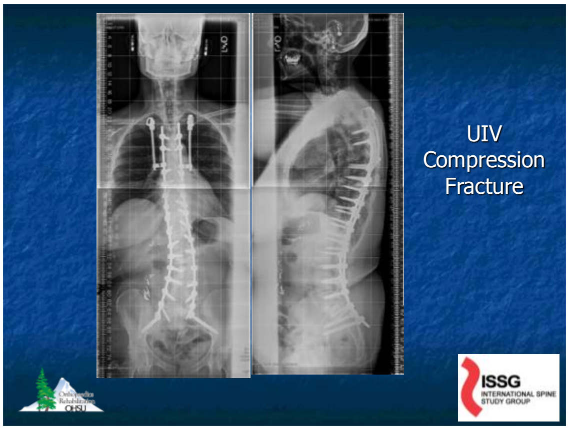
- Rib Attachment UIV+1 Level
- Separate Lateral Incisions
- Blunt Muscle Dissection
- Offset Connection

Personal Experience

- 6 Patients
- 5 Female/1 Male
- Age Range 62-77
- BMI 20.4-42.0
- 1 PJF Without Collapse
- 1 Distal Fracture

Case 1:

62 YO Woman
Degenerative
Normal DEXA
No Prior Surgery


UIV
Compression
Fracture
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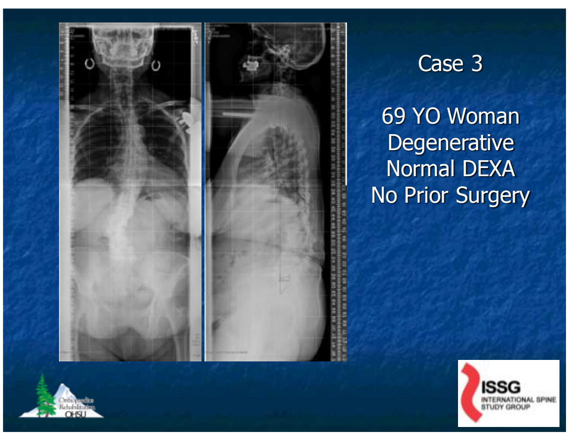
Case 3
69 YO Woman
Degenerative
Normal DEXA
No Prior Surgery
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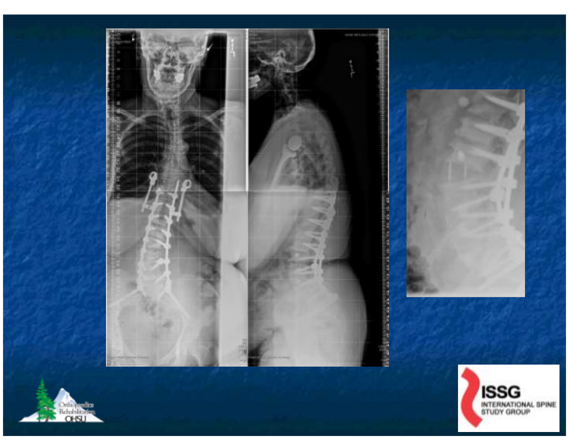
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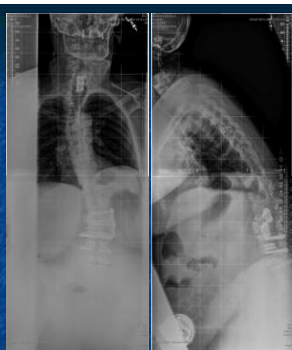


Case 4

67 YO Woman
BMI 42
Osteopenia
Multiple Prior Surg

Conclusions

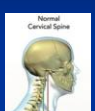
- PJF is a Serious Complication
- Risk Profile Defined
- Methods to Reduce Frequency
- No Technique Eliminates PJF
- Further Development/Study Needed

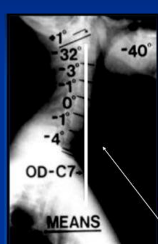

THANK YOU

The Development of the ISSG Cervical Deformity Classification:
The Process Based on Clinical Impact

Christopher Ames MD
Professor
Director of Spine Tumor and Deformity Surgery
UCSF Department of Neurosurgery

Normative and Spinal Pelvic Correlations





Hardacker Spine 1997

	Group 1 (back pain ≤ 3) (°)	Group 2 (back pain > 3) (°)	P Value (t test)	Total (groups 1 and 2) (°)
Cervical standing segmental angular measures				
Segmental level				
O–C1	+2.1 ± 5.0	+0.9 ± 5.5	0.3	+1.5 ± 5.2
C1–C2	−32.2 ± 7.0	−31.7 ± 7.1	0.7	−31.9 ± 7.0
C2–C3	−1.9 ± 5.2	−3.3 ± 4.6	0.2	−2.6 ± 4.9
C3–C4	−1.5 ± 5.0	−1.0 ± 5.8	0.7	−1.2 ± 5.4
C4–C5	−0.6 ± 4.4	+0.3 ± 5.5	0.4	−0.1 ± 5.0
C5–C6	−1.1 ± 5.1	−1.5 ± 4.9	0.7	−1.3 ± 5.0
C6–C7	−4.5 ± 4.3	−4.2 ± 4.6	0.7	−4.3 ± 4.4
Standing total angular measures				
Region				
Cervical	−39.4 ± 9.5	−40.6 ± 9.9	0.5	40.0 ± 9.7
Thoracic	+48.9 ± 11.1	+50.0 ± 10.8	0.6	+49.4 ± 10.9
Lumbar	−61.7 ± 12.2	−58.5 ± 11.9	0.2	−60.1 ± 12.1

Note: Positive values are kyphotic and negative values are lordotic.

Cervical plumb lines from the odontoid to C7 for all 100 volunteers were distributed in a narrow range (16.8 ± 11.2 mm)

Alignment Study Normal Population

- 55 asymptomatic volunteers (27 men, 28 women; mean age=45 years) were evaluated by full-length standing radiographs using a standardized protocol. All radiographs were analyzed using validated image analysis software for C2-C7 cervical lordosis (CL), T4-T12 thoracic kyphosis (TK), L1-S1 lumbar lordosis (LL), pelvic tilt (PT), sagittal vertical axis (SVA), pelvic incidence (PI) and PI-LL mismatch. Statistical analysis was performed for the study population and after stratification by age (20-39yo, 40-59yo and ≥60yo).

Spine Focus Issue 2013
Age related cervical and spino-pelvic parameters variations in a volunteer population

Benjamin Blondel, MD[1,2] Frank Schwab, MD[1] Christopher Ames, MD[3] Jean-Charles Le Huec, MD PhD[4], Justin S. Smith, MD PhD[5] Jason Demakakos, MS[1] Bertrand Moal, MS[1] Patrick Tropiano, MD PhD[2] Virginie Lafage, PhD[1]

Normal Cervical Alignment?

	20-39 years		40-59 years		>60 years		P value
	Mean	SD	Mean	SD	Mean	SD	
Cervical Lordosis (°)	+9.4	9	+6.6	9	+22.2*	9	<0.001
Thoracic Kyphosis (°)	-38.1	11	-36	9	-45	14	NS
Lumbar Lordosis (°)	+61.5	12	+60.3	7	+55.7	13	NS
Pelvic Tilt (°)	12.1	7	14.5	5	15.1	8	NS
Pelvic Incidence (°)	52.1	10	54.3	8	53.5	10	NS
Sacral Slope (°)	40	9	39.9	7	36.5	10	NS
SVA (mm)	-28.5	28	-18.2	39	22.4*	40	<0.001
T1-Slope (°)	-22	7	-21.1	8	-31.6*	9	0.001

able 1: Mean sagittal parameters among the volunteers stratified by age group, p-values refer to ANOVA comparison between groups.

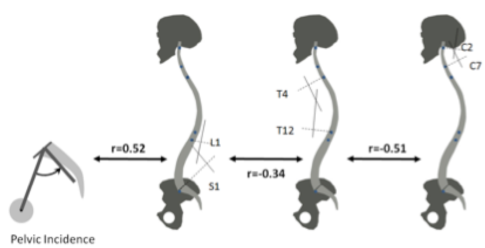


Figure 2: Chain of correlation between PI and regional sagittal parameters. A large PI requires a large lumbar lordosis. An increase of Lumbar lordosis is correlated with an increased thoracic kyphosis which is correlated with an increased cervical lordosis.

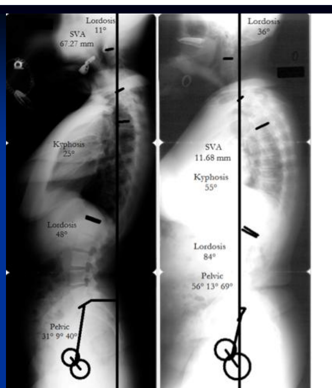
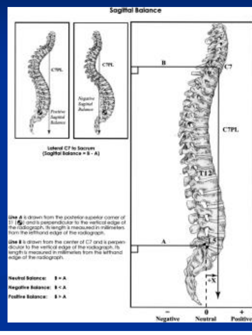


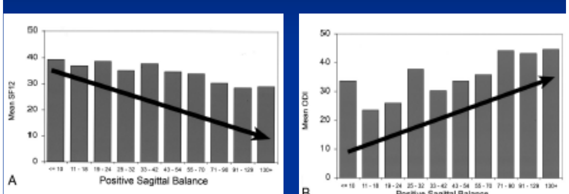
Figure 5: Spino-pelvic chain of correlations, 2 volunteers, well aligned, one with small PI, LL, TK, CL (left) and one with large PI, LL, TK, CL (right)

Background

- Sagittal malalignment linked to disability and unfavorable HRQOL scores
- Glassman *et al* found that sagittal alignment using C7 plumb line is most reliable predictor of HRQOL scores

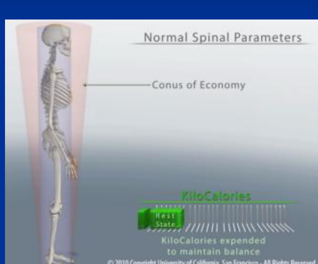


Glassman Data Spine 2005

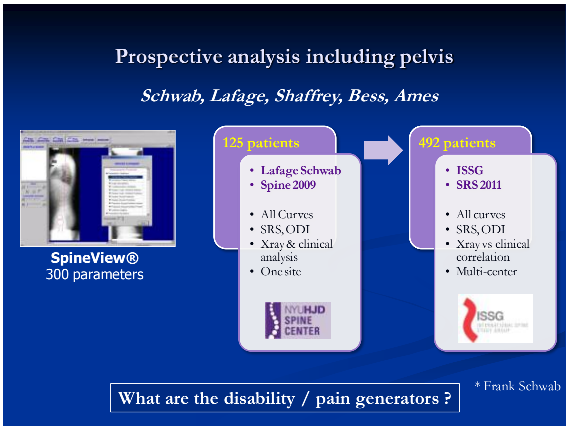


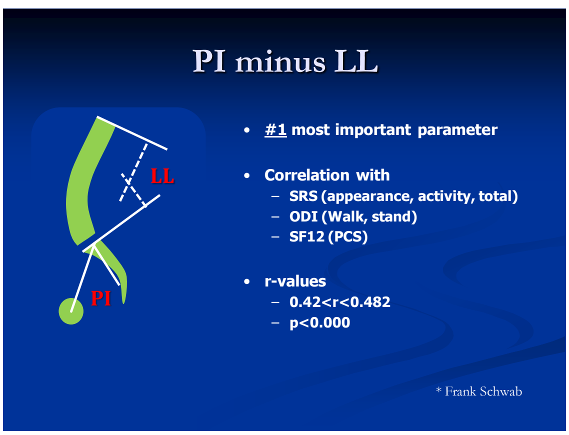
Changing our Treatment Strategies for all T/L patients

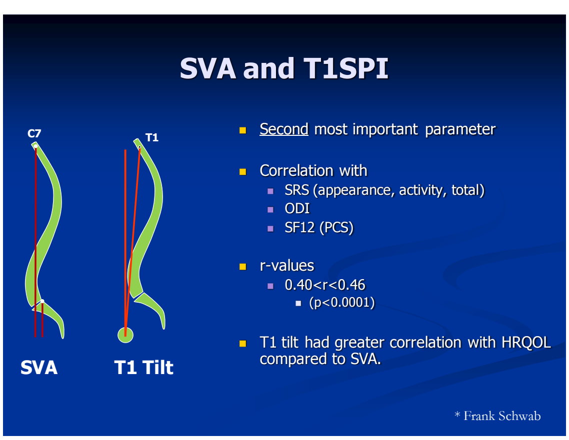
The SRS-Schwab Classification of ASD (2012)



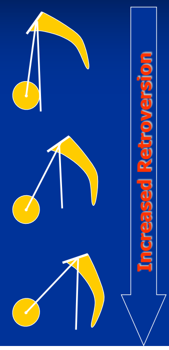
Jean Dubousset


Prospective analysis including pelvis
Schwab, Lafage, Shaffrey, Bess, Ames
SpineView®
300 parameters
125 patients
Lafage Schwab
Spine 2009
All Curves
SRS, ODI
Xray & clinical analysis
One site
NYUHJD SPINE CENTER
492 patients
ISSG
SRS 2011
All curves
SRS, ODI
Xray vs clinical correlation
Multi-center
ISSG
What are the disability / pain generators ?
* Frank Schwab


PI minus LL
LL
PI
#1 most important parameter
Correlation with
SRS (appearance, activity, total)
ODI (Walk, stand)
SF12 (PCS)
r-values
0.42<r<0.482
p<0.000
* Frank Schwab


SVA and T1SPI
C7
T1
SVA
T1 Tilt
Second most important parameter
Correlation with
SRS (appearance, activity, total)
ODI
SF12 (PCS)
r-values
0.40<r<0.46
(p<0.0001)
T1 tilt had greater correlation with HRQOL compared to SVA.
* Frank Schwab

Pelvic Tilt



- Third most important parameter
- Correlation with
  - SRS (appearance, activity, total)
  - ODI (Walk, stand)
  - SF12 (PCS)
- Correlations with HRQOL
  - $0.37<r<0.41$
  - $p<0.000$

* Frank Schwab

SRS-Schwab Classification

Clinical Impact Classification

4 Coronal Curves Type

- T **Thoracic only** with lumbar curve < 30°
- L **TL / Lumbar only** with thoracic curve <30°
- D **Double Curve** with at least one T and one TL/L, both > 30°
- N **No Coronal Curve** All coronal curves <30 °

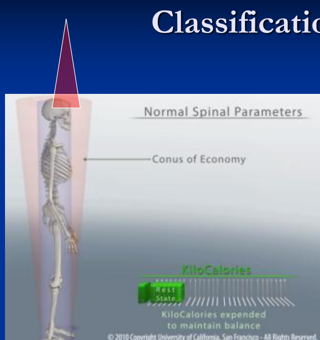
3 Sagittal Modifiers

PI minus LL
- 0 : within 10°
- + : moderate 10-20°
- ++ : marked >20°

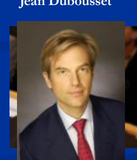
Global alignment
- 0 : SVA < 4cm
- + : SVA 4 to 9.5cm
- ++ : SVA > 9.5cm

Pelvic Tilt
- 0 : PT<20°
- + : PT 20-30°
- ++ : PT>30°

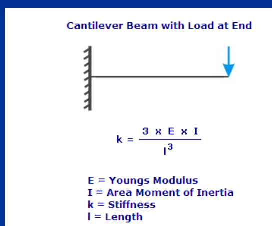
ISSG Cervical Deformity Classification

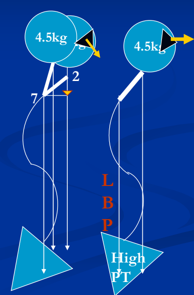


Jean Dubousset



Cantilever Load of Head





The Impact of Standing Regional Cervical Sagittal Alignment on Outcomes in Posterior Cervical Fusion Surgery

Jessica A. Tang, BS*
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Justin S. Smith, MD, PhD**
Vedat Deviren, MD§
Shay Bess, MD¶
Robert A. Hart, MD||
Virginie Lafage, PhD#
Christopher I. Shaffrey, MD**
Frank Schwab, MD#
Christopher P. Ames, MD*
the ISSG

BACKGROUND: Positive spinal regional and global sagittal malalignment has been repeatedly shown to correlate with pain and disability in thoracolumbar fusion.
OBJECTIVE: To evaluate the relationship between regional cervical sagittal alignment and postoperative outcomes for patients receiving multilevel cervical posterior fusion.
METHODS: From 2006 to 2010, 113 patients received multilevel posterior cervical fusion for cervical stenosis, myelopathy, and kyphosis. Radiographic measurements made at intermediate follow-up included the following: (1) C1-C2 lordosis, (2) C2-C7 lordosis, (3) C2-C7 sagittal vertical axis (C2-C7 SVA; distance between C2 plumb line and C7), (4) center of gravity of head SVA (CGH-C7 SVA), and (5) C1-C7 SVA. Health-related quality-of-life measures included neck disability index (NDI), visual analog pain scale, and SF-36 physical component scores. Pearson product-moment correlation coefficients were calculated between pairs of radiographic measures and health-related quality-of-life scores.
RESULTS: Both C2-C7 SVA and CGH-C7 SVA negatively correlated with SF-36 physical component scores ($r = -0.43$, $P < .001$ and $r = -0.36$, $P = .005$, respectively). C2-C7 SVA positively correlated with NDI scores ($r = 0.20$, $P = .036$). C2-C7 SVA positively correlated with C1-C2 lordosis ($r = 0.33$, $P = .001$). For significant correlations between C2-C7 SVA and NDI scores, regression models predicted a threshold C2-C7 SVA value of approximately 40 mm, beyond which correlations were most significant.
CONCLUSION: Our findings demonstrate that, similar to the thoracolumbar spine, the severity of disability increases with positive sagittal malalignment following surgical reconstruction.

KEY WORDS: Cervical fusion, Cervical spine, HRQOL, Radiographic parameters, Sagittal alignment, Spinal deformity

- Goals:
  - Evaluate relationship between sagittal alignment of cervical spine and patient-reported HRQOL scores following multi-level posterior cervical fusion
  - Identify radiographic parameters in cervical spine most predictive of postoperative disability

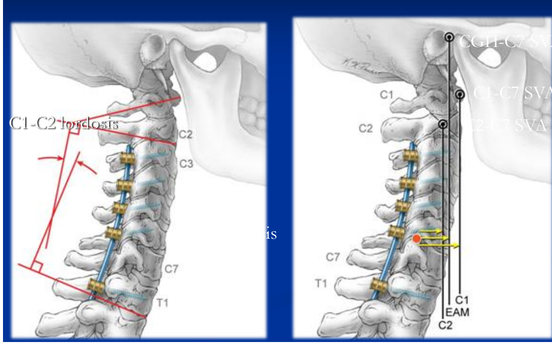
MATERIALS AND METHODS

- Retrospective analysis (2006 – 2010)
- Clinical Outcomes
  - NDI
  - SF-36 PCS
  - VAS
- Radiographic Outcomes
  - C2-C7 Lordosis
  - C2-C7 SVA
  - T1 Slope
  - T1 Slope – C2-C7 Lordosis

Patient Demographics

- 113 patients (M=61, F=52)
- Mean age: 59 ± 12 years
- Most common indications for long segment cervical fusion:
  - Cervical stenosis (n = 65)
  - Myelopathy (n = 38)
  - Deformity (n = 14)
  - Degenerative disc (n = 13)
- Mean number of levels fused: 5.6 ± 1.9
- Average follow-up time: 187 ± 108 days

Cervical Measurements



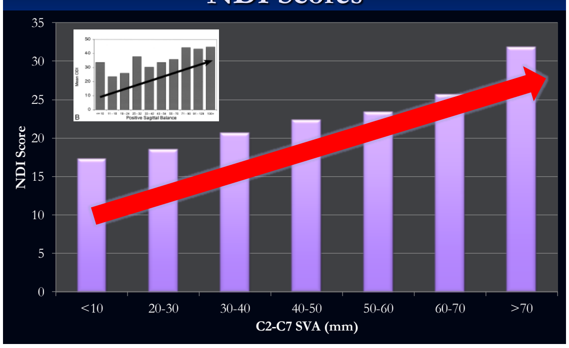
Measurement of cervical SVA

- **C2-C7 SVA**
- Distance between plumb line dropped from centroid of C2 and C7

Significant Correlations: Radiographic Measures and HRQOL Scores

Radiographic Measure	HRQOL Score	No. Cases	Pearson's coefficient	P-value
C1-C7 SVA	NDI	108	0.1863	0.0535
C1-C7 SVA	PCS	58	-0.4097	0.0014*
C2-C7 SVA	NDI	108	0.2015	0.0365*
C2-C7 SVA	PCS	58	-0.4262	0.0009*
CGH-C7 SVA	NDI	108	0.1873	0.0522
CGH-C7 SVA	PCS	58	-0.3613	0.0053*

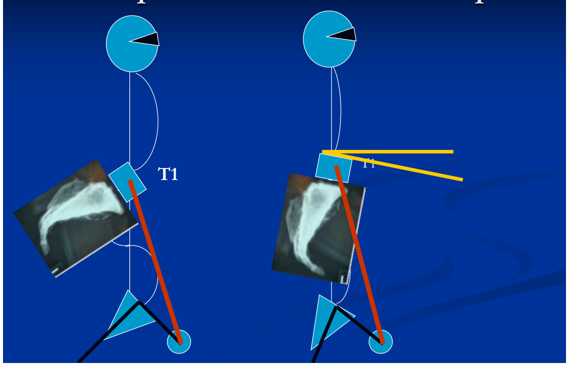
Correlation between C2-C7 SVA and NDI Scores



Background T1-CL

- In the lumbar spine, the single best predictor of disability is a mismatch greater than 11 degrees between lumbar lordosis and pelvic incidence (LL–PI > 11 degrees).
- The T1 slope has been previously suggested as an important factor in influencing overall spinal sagittal alignment, and increasing T1 slope has been shown to significantly correlate with greater sagittal malalignment of the dens (Knott *et al*, 2010).

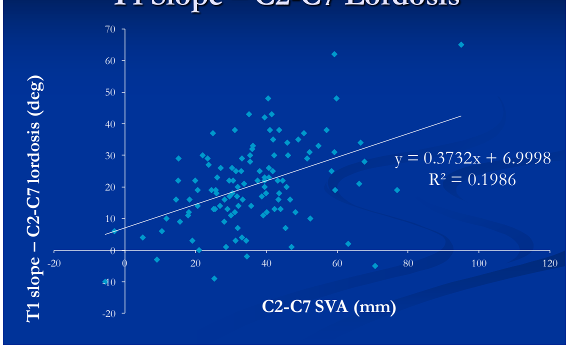
Concept CT "Incidence"-T1 slope



Significant Correlations: Radiographic Measures

Radiographic Measure	Radiographic Measure	Pearson's coefficient	P-value
C2-C7 Lordosis	T1 Slope	0.38	<0.0001*
C2-C7 SVA	T1 Slope	0.44	<0.0001*
C2-C7 SVA	T1 Slope – C2-C7 Lordosis	0.45	<0.0001*

Correlation between C2-C7 SVA and T1 Slope – C2-C7 Lordosis



Regression Analysis for Disability Thresholds

- Significant correlations further analyzed between C2-C7 SVA and NDI scores ($n = 108$)
- Logistic regression model predicted threshold value of 41 mm for C2-C7 SVA ($\chi^2 = 6.60$, $p = 0.0102$)
- Linear regression predicted threshold C2-C7 SVA value of 37 mm for a raw NDI score of 25 ($r^2 = 0.04$, $p = 0.0365$)
- C2-C7 SVA value of 40mm corresponded to a T1 slope – C2-C7 lordosis value of **21.9 deg**.

DISCUSSION

- Positive cervical sagittal malalignment, measured by C2-C7 SVA, negatively affects HRQOL scores following multi-level posterior cervical fusion at intermediate follow-up
- Study proposes a C2 plumb line greater than ~40 mm from posterior superior aspect of C7 (in standing position) suggests clinical concern of cervical sagittal malalignment that may negatively impact HRQOL

DISCUSSION

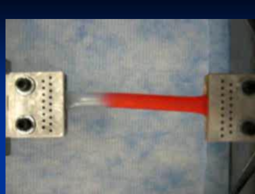
- The greater the T1 slope, the greater C2-C7 lordosis (perhaps a compensatory mechanism?)
- The greater the mismatch between T1 slope and C2-C7 lordosis, the greater the sagittal mal-alignment
- *cSVA >4cm*
- *T1 slope –CL > 20 = cSVA>4cm*

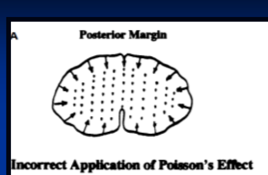
Question?

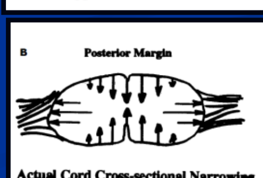
- Is it enough to simply decompress patients with myelopathy and kyphosis or is it more beneficial to also correct their deformity?
  - For neck pain and disability
  - For myelopathy improvement
  - For adjacent segment disease
- If so, what parameters do we use?
- How do we do it if the spine is rigid?

Cervical alignment: myelopathy

- Common etiology: multi-level spondylosis
- Less attention to progressive cervical kyphosis – also associated with myelopathy







Association of Myelopathy Scores with Cervical Sagittal Balance and Normalized Spinal Cord Volume

Analysis of 56 Preoperative cases from the AOSpine North America Myelopathy Study

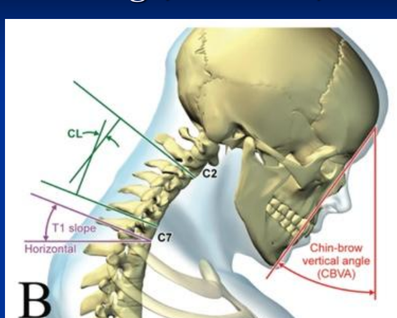
Justin Smith, MD, PhD
Virginie Lafage, PhD
Christopher Shaffrey, MD
Frank Schwab, MD
Dan Riew, MD
VincentTraynelis
Alex Vaccaro, MD, PhD
*Michael Fehlings, MD, PhD
Christopher Ames, MD

AO Foundation

Results: Correlations between mJOA and Sagittal Radiographic Parameters

Parameter	Pearson Correlation	p-value
C2-C7 SVA (mm)	-0.282**	0.035
C1-C7 SVA (mm)	-0.286**	0.033
Center of gravity-C7 SVA (mm)	-0.207	0.125
C2 tilt (°)	-0.272**	0.043
C2 slope (°)	-0.281**	0.036
C7 slope (°)	-0.191	0.158
T1 slope (°)	-0.176	0.194
C2-C7 Cobb angle (°)	0.040	0.770
C2-C7 Harrison angle (°)	0.045	0.742
T1 slope minus C2-C7 Cobb angle (°)	-0.234	0.083
T1 slope minus C2-C7 Harrison angle (°)	-0.213	0.116
Posterior length (mm)	0.185	0.172
Anterior length (mm)	0.197	0.146
Anterior length / posterior length	0.060	0.662

Self Image, Function, CBVA



Impact of Subjacent Alignment

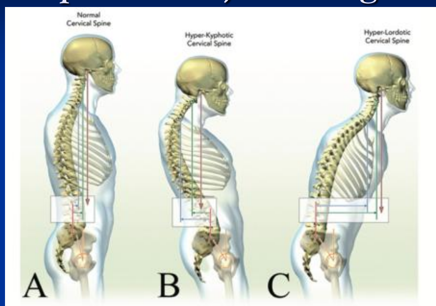
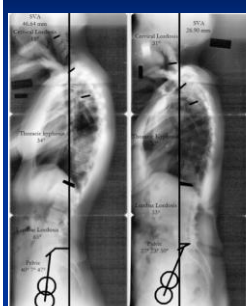


Fig. 11. Proper sagittal alignment facilitates posture maintenance, and poor alignment can lead to compensatory mechanisms that alter alignment parameters of the cervical spine. An elevated pelvic tilt is produced by either cervical kyphosis or global sagittal malalignment, but pelvic tilt due to cervical kyphosis is usually accompanied by lumbar hyperlordosis.

PT and CL



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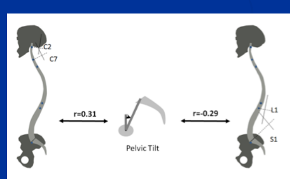
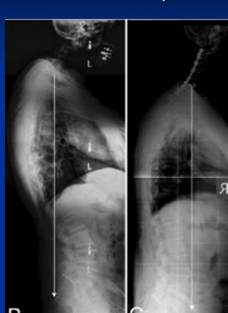
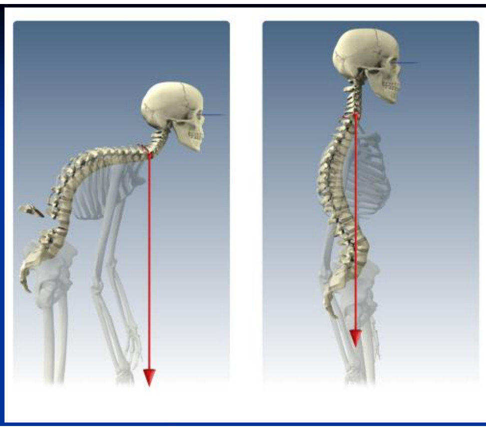


ure 3: Correlation between Pelvic Tilt and regional sagittal parameters. A loss of lumbar lordosis is correlated ith a pelvic retroversion acting as compensatory mechanisms. Pelvic retroversion is also correlated with an increased cervical lordosis.

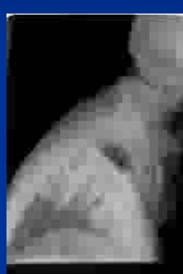
Subjacent Alignment



- Cervical Alignment depends on subjacent alignment
- Pelvic retroversion and lumbar hyperlordosis in primary cervical deformity
- Cervical correction results in improvement in normalization of compensatory parameters



Example Case—Correction of Cervical Hyperlordosis with Lumbar PSO



J Neurosurg Spine 17:300–307, 2012

Spontaneous improvement of cervical alignment after correction of global sagittal balance following pedicle subtraction osteotomy

Presented at the 2012 Joint Spine Section Meeting

Clinical article

Justin S. Smith, M.D., Ph.D.,[1] Christopher I. Shaffrey, M.D.,[1] Virginie Lafage, Ph.D.,[2] Benjamin Blondel, M.D.,[2] Frank Schwab, M.D.,[2] Richard Hostin, M.D.,[3] Robert Hart, M.D.,[4] Brian O'Shaughnessy, M.D.,[5] Shay Bess, M.D.,[6] Serena S. Hu, M.D.,[7] Vedat Deviren, M.D.,[7] Christopher P. Ames, M.D.,[8] and International Spine Study Group

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Radiographic Parameter	Mean ± SD Preop	Mean ± SD Postop	p Value*
C2–3 angle (°)	4.4 ± 4.6	3.7 ± 4.2	0.34
C2–7 angle (°)	30.8 ± 11.7	21.6 ± 14.5	<0.001
C2–7 plumb line (mm)	27.0 ± 21.5	22.9 ± 16.8	0.033
T-1 slope (°)	−38.9 ± 11.3	−30.4 ± 11.2	<0.001
T2–12 angle (°)	−35.7 ± 20.2	−48.0 ± 16.2	<0.001
T12–S1 angle (°)	17.4 ± 19.0	49.3 ± 15.1	<0.001
C2–S1 plumb line (mm)	189.2 ± 59.7	73.4 ± 56.6	<0.001
C7–S1 plumb line (mm)	163.8 ± 56.1	51.8 ± 52.8	<0.001
T-1 spinopelvic inclination (°)	5.5 ± 5.2	−2.9 ± 5.2	<0.001
C3–7 inclination (°)	19.9 ± 18.9	18.1 ± 20.7	0.37
C7–T12 inclination (°)	28.8 ± 18.1	9.5 ± 8.3	<0.001
T12–S1 inclination (°)	1.3 ± 13.4	−4.7 ± 9.6	<0.001
PT (°)	32.5 ± 8.8	23.9 ± 8.7	<0.001
SS (°)	24.5 ± 11.9	33.6 ± 9.7	<0.001

Cervical Deformity Classification

ISSG International Spine Study Group

Deformity Descriptor

- **C**- Primary Sagittal Deformity Apex in Cervical Spine
- **CT**- Primary Sagittal Deformity Apex at Cervico-Thoracic Junction
- **T**- Primary Sagittal Deformity Apex in Thoracic Spine
- **S**- Primary Coronal Deformity (C2-C7 Cobb ≥ 15°)
- **CVJ**- Primary Cranio-Vertebral Junction Deformity

5 Modifiers

- **C2-C7 sagittal vertical axis (SVA)**
  - **0**: C2-C7 SVA < 4cm
  - **1**: C2-C7 SVA 4 to 8cm
  - **2**: C2-C7 SVA > 8cm
- **Horizontal Gaze**
  - **0**: CBVA < ° 10
  - **1**: CBVA 10 to 25°
  - **2**: CBVA > 25 °
- **Cervical Lordosis Minus T1 Slope**
  - **0**: CL-T1 < ° 15
  - **1**: CL-T1 15-to 20 °
  - **2**: CL-T1 >20 °
- **Myelopathy**
  - **0**: mJOA=18 (None)
  - **1**: mJOA=15-17 (Mild)
  - **2**: mJOA=12-14 (Moderate)
  - **3**: mJOA<12 (Severe)
- **SRS-Schwab Classification**
  - **T, L, D, or S**: Curve Type
  - **A, B, or C**: LL minus PI
  - **L, M, or H**: Pelvic Tilt
  - **N, P, or VP**: C7-S1 SVA

Treatment of *Adult Cervical* Deformity Based on Classification?

ISSG INTERNATIONAL SPINE STUDY GROUP

Exhibit A: Study Protocol

Prospective Radiographic and Clinical Evaluation of Surgical Treatment for Cervical Deformity: A Multi-Center Study

Lead-Principal Investigator: [illegible]

Co-Principal Investigators: [illegible]

Co-Investigators: [illegible]

Specific Aims:

- Define clinical and demographic features of the population afflicted with cervical deformity (e.g., age, gender, comorbidities, disability, health related quality of life)
- Assess for correlations between radiographic parameters and degree of disability/pain at baseline
- Assess and describe surgical strategies used to address cervical deformity
- Assess the role/utility of preoperative traction in surgery for cervical deformity
- Define complications and rates of complications (perioperative and delayed) associated with the surgical treatment of cervical deformity
- Assess the role/need for pre/post operative tracheosotomy and PEG
- Define baseline swallowing function, compare with postoperative function, and assess for changes over two-year follow up interval (based on CSRS SWAL-QOL)
- Evaluate and compare radiographic changes of sagittal spinal alignment (focal, regional, and global) and pelvic parameters pre and post cervical deformity surgery.
- Develop predictive formulas of post-operative alignments based on surgical techniques employed for correction
- Identify risk factors related to poor clinical outcomes
- Define potential impact of complications on clinical/radiographic outcomes
- Determine reoperation rates over two-year follow-up period
- Assess change in subaxial alignment after occiput to C2 fusion
- Assess the effect of C1-2 lordosis and C1-2 fusion on subaxial alignment and outcome
- Assess outcomes of long fusions involving the occiput related to head center of gravity and regional and global balance
- Assess outcomes of occipital-cervical-thoracic fusion on cervical alignment and global alignment
- Evaluate clinical outcomes (up to 2 years) following cervical deformity surgery

- Inclusion criteria: (Must meet all criteria as outlined in 1-4):
- 1) Adult patients (≥18 years old at time of enrollment)
- 2) Cervical deformity- must meet one or more of the following criteria:
  - Cervical kyphosis (C2-7 Cobb angle >10°)
  - Cervical scoliosis (coronal Cobb angle >10°)
  - cSVA > 4 cm
  - CBVA > 25°
- 3) Plan for surgical correction of cervical deformity

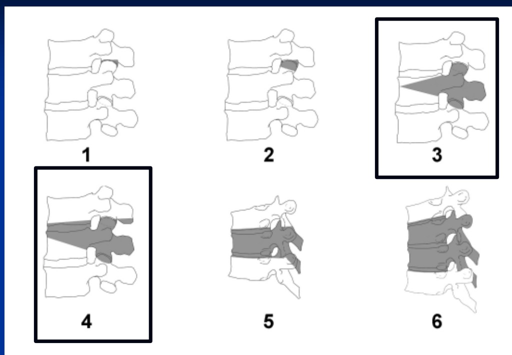
Standardized Questionnaires):
NDI, NRS, CSRS SWAL-QOL, EQ-5D, mJOA

Nomenclature— Cervical Osteotomy Classification

Osteotomy Grades and Surgical Approach Modifiers-Schwab

	Resection	Description	Surgical approach
Grade 1	Partial Facet Joint	Resection of the inferior facet and joint capsule at a given spinal level	A/P (anterior soft tissue release combined with posterior resection) P (posterior)
Grade 2	Complete Facet Joint	Both superior and inferior facets at a given spinal segment are resected; other posterior elements of the vertebra including the lamina, and the spinous processes may also be resected	A/P (anterior soft tissue release combined with posterior resection) P (posterior)
Grade 3	Partial Body	Partial wedge resection of a segment of the vertebral body and a portion of the posterior vertebral elements	A (anterior release) P (posterior release) A/P (both)
Grade 4	Partial Body and Disc	wedge resection through the vertebral body; includes a substantial portion of the vertebral body, posterior elements and includes resection of at least a portion of one endplate with the adjacent intervertebral disc	A (anterior release) P (posterior release) A/P (both)
Grade 5	Complete Body and Disc	Complete removal of a vertebral body and both adjacent discs (rib resection in the thoracic region)	A (anterior release) P (posterior release) A/P (both)
Grade 6	Multiple Adjacent Body	Resection of more than one entire vertebral body and discs. Grade 5 resection and additional adjacent vertebral resection	A (anterior release) P (posterior release) A/P (both)

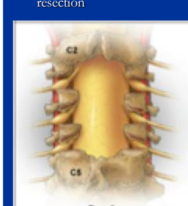
Osteotomy Grade Representation-Schwab



	Resection	Description	Surgical approach
Grade 1	Partial Facet Resection or ACD	Anterior cervical discectomy including partial uncovertebral joint resection, posterior facet capsule resection or partial facet resection	A, P, PA, AP, APA, PAP
Grade 2	Complete Facet Joint/Ponte Osteotomy	Both superior and inferior facets at a given spinal segment are resected; other posterior elements of the vertebra including the lamina, and the spinous processes may also be resected	A,P, PA, AP, APA, PAP
Grade 3	Partial Body, Corpectomy	Partial Corpectomy Including discs above and below	A,P, AP, PA, APA, PAP
Grade 4	Complete Uncovertebral Joint Resection to Foramen Transversarium	Anterior osteotomy through lateral body and uncovertebral joints and into foramen transversarium	A,P, AP, PA, APA, PAP
Grade 5	Opening Wedge Osteotomy	Complete posterior element resection with osteoclastic fracture and open wedge creation	A, P, AP, PA, APA, PAP
Grade 6	Closing Wedge Osteotomy	Complete posterior element resection and pedicle resection with closing wedge creation	A, P, AP, PA, APA, PAP
Grade 7	Complete Vertebral Column Resection	Resection of one or more entire vertebral body and discs including complete uncovertebral joint and posterior lamina and facets	A, P, AP, PA, APA, PAP

Case 11

Operative procedure:
Posterior spinal fusion with instrumentation from C2-T2, multilevel complete facet resection

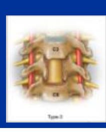


Case 19

Operative procedure:
Posterior instrumentation from C2-T8, pedicle subtraction osteotomy at C7, posterior spinal osteotomy at C6-T1

Case 16

Stage 1: C4-5 corpectomy followed by
Stage 2: Posterior spinal fusion with instrumentation from C2-T2 and ponte osteotomy



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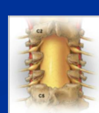
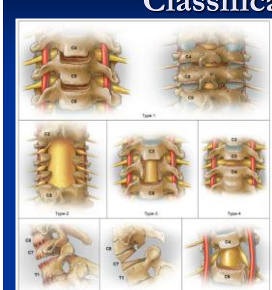


ISSG Cervical Osteotomy Classification



JNS Spine September 2013

- Analysis of major osteotomy + approach modifier yielded a classification that was "almost perfect" with average intra-rater reliability of 0.91 (0.82-1.0) and inter-rater reliability of 0.87 and 0.86 for the 2 reviews.

Further Reading

ISSG
INTERNATIONAL SPINE STUDY GROUP

J Neurosurg Spine 19:141–159, 2013

Cervical spine alignment, sagittal deformity, and clinical implications

A review

Justin K. Scheer, B.S.,[1] Jessica A. Tang, B.S.,[1] Justin S. Smith, M.D., Ph.D.,[2] Frank L. Acosta Jr., M.D.,[3] Themistocles S. Protopsaltis, M.D.,[4] Benjamin Blondel, M.D.,[5] Shay Bess, M.D.,[6] Christopher I. Shaffrey, M.D.,[2] Vedat Deviren, M.D.,[7] Virginie Lafage, Ph.D.,[4] Frank Schwab, M.D.,[4] Christopher P. Ames, M.D.,[8] and the International Spine Study Group

[1]School of Medicine, University of California, San Diego, California; [2]Department of Neurosurgery, University of Virginia Health System, Charlottesville, Virginia; [3]Department of Neurological Surgery, Cedars-Sinai Medical Center, Los Angeles, California; [4]Department of Orthopaedic Surgery, NYU Hospital for Joint Diseases, New York, New York; [5]Université Aix-Marseille, Marseille, France; [6]Rocky Mountain Hospital for Children, Denver, Colorado; and Departments of [7]Orthopedic Surgery and [8]Neurological Surgery, University of California, San Francisco, California

Surgical Treatment of Pathological Loss of Lumbar Lordosis (Flatback) in the Setting of Normal SVA Achieves Similar Clinical Improvement as Surgical Treatment for Elevated SVA

Justin S. Smith, Manish Singh, Eric Klineberg, Christopher I. Shaffrey, Virginie Lafage, Frank Schwab, Themi Protopsaltis, David Ibrahimi, Justin K. Scheer, Greg Mundis, Munish Gupta, Richard Hostin, Vedat Deviren, Khaled Kebaish, Robert Hart, Doug Burton, Shay Bess, Christopher Ames

University of Virginia Health System

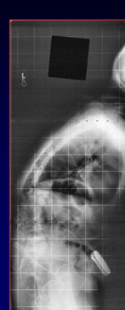
ISSG International Spine Study Group

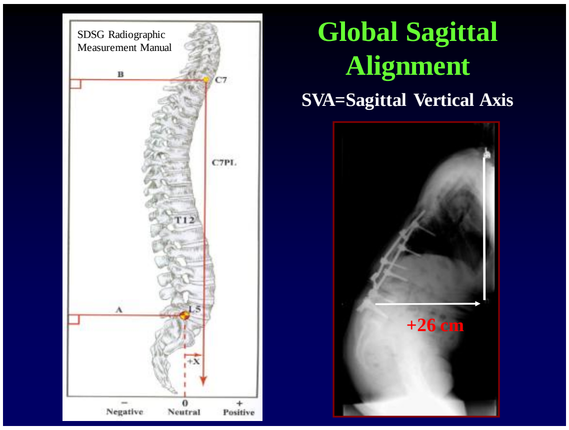
Disclosures

- Biomet: consultant, honorarium for teaching
- Medtronic: consultant, honorarium
- DePuy: consultant, research study group support
- Globus: honorarium for educational course
- AANS/CNS Joint Spine Section: research grant support

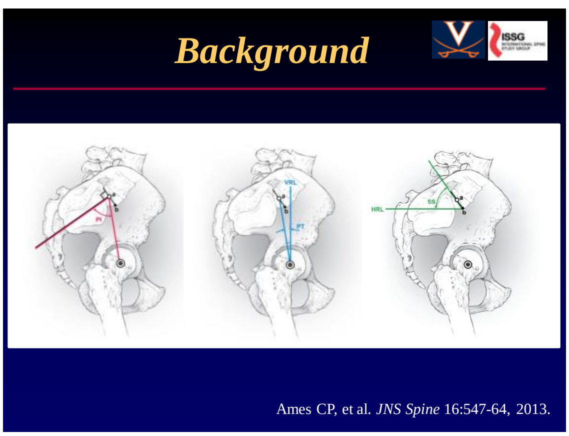
Background

- **Sagittal spinal malalignment is a key driver of pain and disability in adult spinal deformity**
- **More recently has become clear that SVA alone does not fully account for global alignment**
- **Role of the pelvis as a key regulator of spinal alignment and a source of compensation**

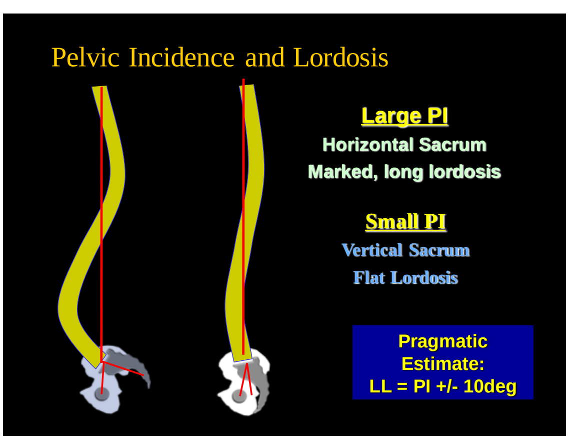




SDSG Radiographic Measurement Manual
B
C7
C7PL
T12
A
L5
+X
Negative
Neutral
Positive
Global Sagittal Alignment
SVA=Sagittal Vertical Axis
+26 cm



Background
PI
VRL
PT
HRL
SS
Ames CP, et al. JNS Spine 16:547-64, 2013.

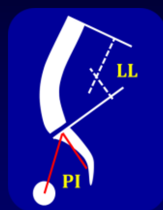


Pelvic Incidence and Lordosis
Large PI
Horizontal Sacrum
Marked, long lordosis
Small PI
Vertical Sacrum
Flat Lordosis
Pragmatic Estimate:
LL = PI +/- 10deg

Background

- Based on 492 adults with spinal deformity, the top radiographic parameters with strongest correlations to HRQOL scores:
  - #1. PI minus LL
  - #2. SVA (C7 plumbline)
  - #3. Pelvic tilt (PT)

PI minus LL



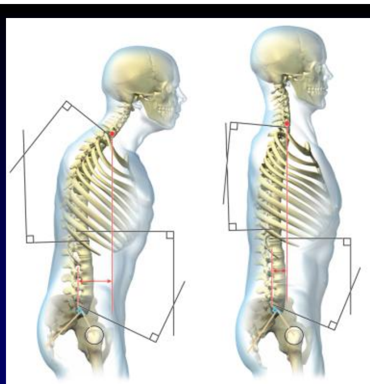
Schwab FL, et al. *Spine* 38(13):E803-12, 2013.

Background

- "Sagittal imbalance" (SVA >5cm) is a recognized driver of disability and a primary indication for surgical correction
- Multiple studies have demonstrated improvement in HRQOL with correction of "sagittal imbalance"

Background

- Subset of patients with sagittal spino-pelvic malalignment and flat back deformity but remains sagittally compensated with normal SVA
- Few data exist for patients with "compensated flatback" (SVA <5cm, PI-LL >10°)
- Does surgical treatment offer improvement in HRQOL?



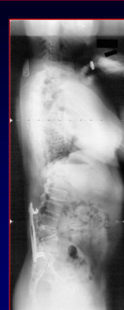
Decompensated Compensated

Objective

- To compare baseline disability and treatment outcomes for patients with sagittal spino-pelvic malalignment who are:
  - **Compensated** **(PI-LL>10˚ & SVA<5cm)**
  - **Decompensated** **(SVA>5cm)**

Methods

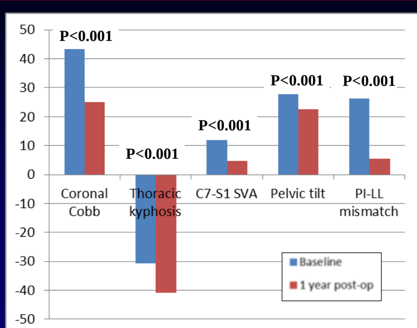
- Study design: Prospective, multi-center (ISSG), consecutive cases
- Inclusion criteria:
  - ASD (age >18)
  - >5 levels posterior instrumentation
  - min 1yr follow-up
  - SVA>5cm (decompensated) OR SVA<5cm with PI-LL>10˚ (compensated)
- Analysis: Comparisons between compensated and decompensated



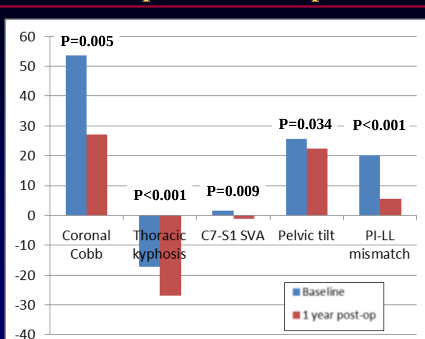
Patient Population

Parameter	SVA > 5cm (n=98)	SVA <5cm & PI-LL >10˚ (n=27)	P-value
Mean age, years (SD)	62.9 (12.4)	55.1 (12.1)	**0.004**
Gender, percent women	76	93	0.063
Mean BMI (SD)	28.6 (5.1)	26.6 (5.9)	0.097
Mean Charlson Comorbidity Index (SD)	1.6 (1.7)	1.1 (1.2)	0.083
Mean pain score, 0-10 (SD)			
Back pain	7.7 (2.0)	6.8 (2.4)	0.060
Leg pain	4.6 (3.2)	4.6 (3.6)	0.97

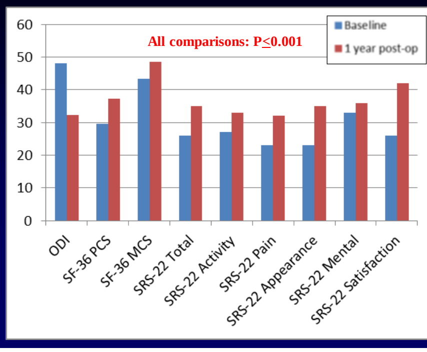
Change from Baseline to 1yr Decompensated Group



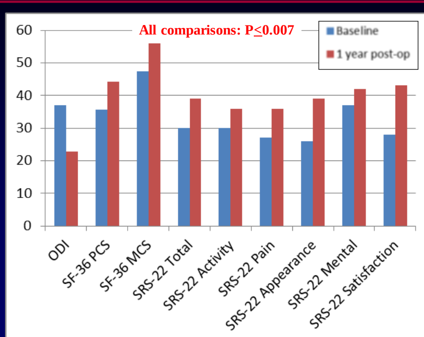
Change from Baseline to 1yr Compensated Group



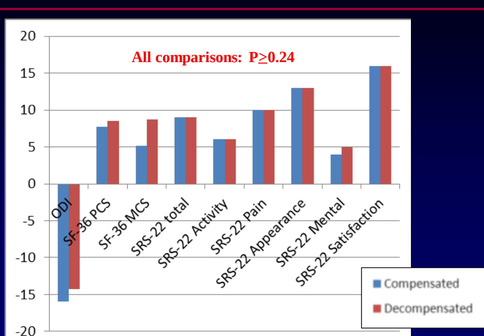
Change from Baseline to 1yr Decompensated Group



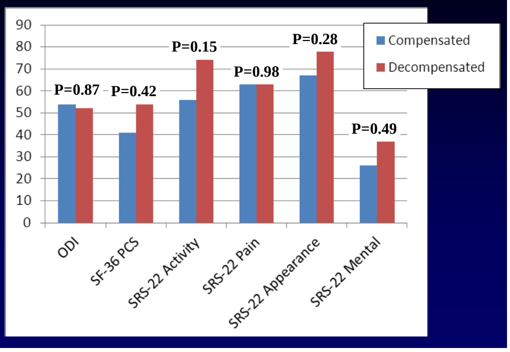
Change from Baseline to 1yr Compensated Group



Change from Baseline to 1yr

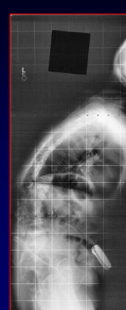


Percent Reaching MCID



Conclusions

- **Sagittal spino-pelvic malalignment is a key driver of pain and disability in adult spinal deformity.**
- **Surgical correction of sagittal spino-pelvic malalignment for compensated and decompensated patients had similar radiographic and HRQOL improvement.**
- **PI-LL mismatch should be evaluated for adult deformity patients and can be considered a primary surgical indication.**



Realignment Failure
What the Research Shows and Future Directions for Analysis and Improvement

Virginie Lafage, PhD
Frank Schwab, MD

Disclosures

- Virginie Lafage
  - (a) SRS
  - (b) Medtronic
  - (c) Nemaris
  - (f) DepuySpine, Medtronic, K2M, Globus
- Frank Schwab
  - (a) DePuy Spine, Medtronic
  - (b) Medtronic
  - (c) Nemaris
  - (f) Medtronic

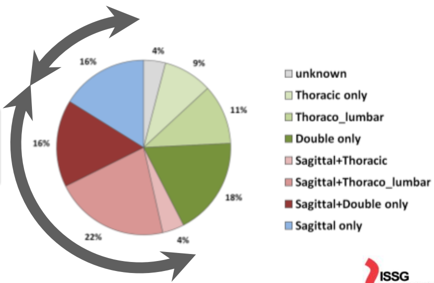
a. Grants/Research Support
b. Consultant
c. Stock/Shareholder
d. Royalties
e. Board member
f. Payment for lectures

1 Correction of Sagittal Plane Deformity Performance Review

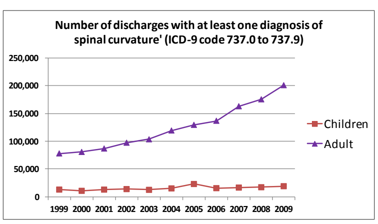
Sagittal Plane Deformity

Prospective Surgical ASD database

~60% of all ASD patients with sagittal deformity

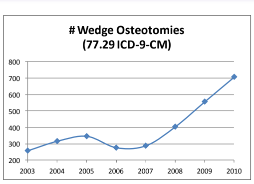


Number of ASD Procedures increased by 157% in 10 years

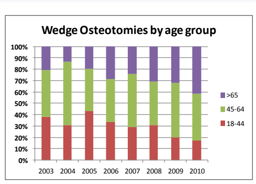


Healthcare Costs and Utilization Project (HCUP http://hcupnet.ahrq.gov),

Utilization of wedge osteotomies



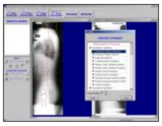
Increases on 275% in less than 10 years
~250 procedures in 2003
~700 procedures in 2012



Increase proportion of patients >65yo
~20% in 2003
~40% in 2012

Radiographic "Drivers" of Disability?

Schwab, Lafage, Shaffrey, Bess, Ames …



SpineView®
300 parameters

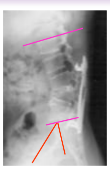
125 patients
- Lafage Schwab
- Spine 2009

- All Curves
- SRS, ODI
- Xray & clinical analysis
- One site

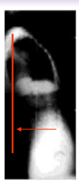
492 patients
- ISSG
- SRS 2011

- All curves
- SRS, ODI
- Xray vs clinical correlation
- Multi-center

Adult Deformity = Disability?



Regional
Loss of lordosis Versus PI



Global
SVA

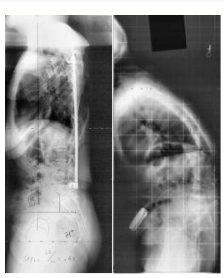
Compensatory
Pelvic tilt

Goals

PI-LL < 10°	SVA < 5cm	PT < 20-25°

Achieving Realignment Goals

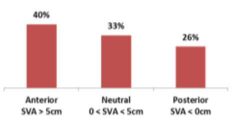
- **As a Surgeon, I know the "alignment objectives"**
  - LL within 10deg of PI
  - PT <20-25deg
  - SVA < 5cm
- **As a Surgeon, I can change focal alignment**
  - Impact on region
  - Impact on global
  - Reset compensation



NYU Langone Medical Center

Effectiveness of sagittal correction

Outcomes after major realignment surgeries



Categorization by SVA post-op

- **Under-correction (SVA)**
  - 40% at 3m following index procedure
- **Analysis of risk factors**
  - Lack of lordosis versus PI
  - 80% can be predicted
- **Root Cause analysis?**
  - Poor planning
  - Poor execution,
  - Intra-op complications
  - Unrealistic Planning
  - Poor intra-op feedback ….

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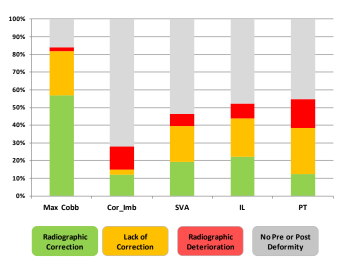
Radiographic Surgical Outcomes

Prospective Surgical ASD database (pre / 1y post-op)



High Frequency of inadequate sagittal correction

Where does the 'problem' come from?

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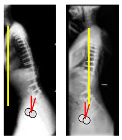
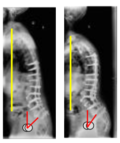
2 Root Cause Analysis

Lumbar Realignment Failures

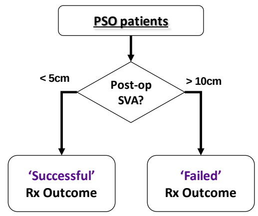


Sagittal Correction
→ HRQOL Improvement

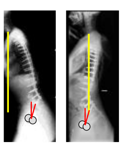


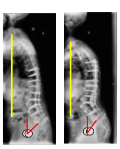
Sub-optimal SVA Correction

Risk factors for realignment failure?



Analysis of the "Failed" Group





- Same Pre-op curvatures
  - Lordosis, kyphosis
- More Pre-op spino-pelvic mal-alignment
  - Proportion Lordosis vs Pelvic Incidence
  - Pelvic retroversion
  - SVA (C7 plumbline)
- Same Surgical Procedure !

Need to establish a quality control process

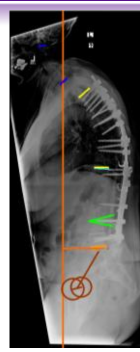
Quality control Process

- **Pre-op Analysis**
  - Evaluate the severity of the deformity
  - Identify / Quantify compensatory mechanisms
- **Pre-op Planning to reach alignment objectives**
  - Changes in lumbar lordosis
  - Changes in thoracic kyphosis
    - Fused segments
    - Reciprocal changes
- **Intra-op monitoring**
  - Patient ;-)
  - Regional alignments
- **Post-op Analysis**
  - Repeat Pre-op analysis
  - Comparison with planning and intra-op xrays

NYU Langone MEDICAL CENTER

1-Pre-op Analysis

- **Requirements**
  - Full length AP / Sagittal Xrays
  - Free standing position
  - Cervical Spine to Acetabulum
- **Spino-Pelvic Parameters**
  - Global Alignment
  - Driver of the deformity
    - Lordosis versus Pelvic Incidence
  - Compensatory mechanism
    - Pelvic Tilt
    - Cervical …



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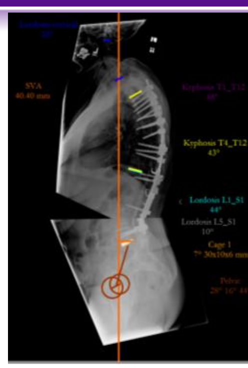
2- Pre-op Planning

- **Objectives**
  - Correct regional / Focal deformity
  - Correct Global alignment
  - Restore hip extension reserve
    - i.e. correct PT
- **Concept**
  - Direct correction of regional spinal curvatures (LL and TK)
  - Indirect correction of PT and SVA
- **Formula(s)**
  - Takes into account correlations between parameters
    - Complex
    - As easy as matching LL with PI



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3- Intra-Op Monitoring

- **Fluoro**
  - During Surgery
  - Lordosis / Kyphosis
    - Focal
    - Regional
- **Long Cassettes**
  - At the end of the case
  - Sagittal **and** Coronal plane
  - Regional curves
  - Compare with planning
- **Surgery vs. objectives**
  - Several methods to reach objectives!
  - Tracking of adverse events

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4- Post-op Analysis

- **Radiographic analysis**
  - Spino-pelvic parameters below/above 'ideal' tresholds?
  - Compensatory mechanisms
    - Pelvis
    - Cervical spine
    - …
- **Root cause analysis**
  - Post-op versus Planning
  - Post-op versus Intra-op
  - …..

Root cause analysis findings

- **Complex deformity can be analyzed by key parameters**
- **Formulas permit prediction of alignment outcome**
- **Pre operative planning optimizes chance of success**
- **Gaps From theory to operative intervention and follow up**
  - Quality of intra op images can limit verification
  - Reciprocal changes in non-fused portions of spine
  - Junctional issues
  - Other?
- **Next steps:**
  - Improved patient specific models including reciprocal changes
  - Improved intra op feedback on alignment with pre op plan

3 Conclusion

NYU Langone MEDICAL CENTER

Conclusion

- **A new landscape**
  - Substantial increase in ASD patients seeking treatment
    - Life expectancy, quality of life expectation
  - Increased rate of complex surgery (osteotomies)
  - Scrutiny on outcomes, complications, cost
- **Better understanding of ASD**
  - Health impact, disability drivers
  - Ability to quantify, classify, treat: spino-pelvic parameters
- **How can we reduce realignment failure**
  - Education is key
  - Patient evaluation
  - Surgical strategy: planning
  - Research translation into practice
    - Optimizing patient modeling, planning, technique
    - Defining acceptable trade-offs: risk vs. benefit

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Minimally Invasive Treatment of Adult Deformity: Research Update and Treatment

Gregory M. Mundis Jr., M.D.
San Diego Center for Spinal Disorders
La Jolla, CA

VuMedi Webinar, August 5, 2013

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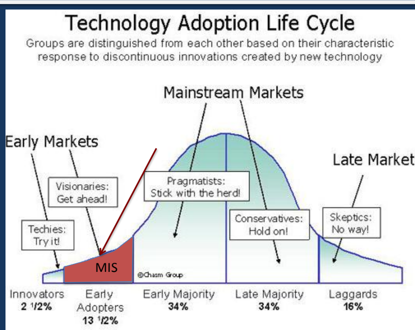
DISCLOSURES

- Consulting: NuVasive, K2M
- Royalties: NuVasive, K2M
- Research/Fellowship support: NuVasive, Pioneer, OREF, ISSGF

MIS like a MAC?

The Chasm



Geoffrey Moore, *Crossing the Chasm*, 1999

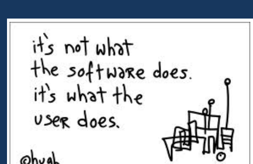
An Exploratory Effort

- Lit Search: 2021 articles with minimally invasive spine surgery
- Predominantly single center retrospective studies
- Little long term data
- No prospective Level 1 data to date

Literature search as of August 3, 2013

MIS The Answer?

- Perhaps a means to an end
- Cannot abandon the principles of deformity correction
- MIS is an approach to reach the same goal



PLANNING, PLANNING, PLANNING

1. Measure all key parameters
2. Quantify the deformity (sagittal and coronal)
3. Evaluate clinical options
   - Fixation options
   - Osteotomies
   - Biologic issues
4. Execute plan…
   - The value of intraoperative scoliosis xrays

What are the limitations?

- Coronal
- Sagittal
- Long segment/pelvic fixation
- Osteotomies
- Fusion/Biology

Is There a Patient Profile That Characterizes a Patient as a Candidate for Minimally Invasive Surgery (MIS) to Treat Adult Spinal Deformity (ASD)?

__Robert K. Eastlack, MD__; Gregory M. Mundis, Jr., MD; Michael Y. Wang, MD; Praveen V. Mummaneni, MD; Juan S. Uribe, MD; David O. Okonkwo, MD, PhD; Behrooz A. Akbarnia, MD; Neel Anand, MD; Adam S. Kanter, MD; Paul Park, MD; Virginie Lafage, PhD; Christopher I. Shaffrey, MD; Richard G. Fessler, MD; Vedat Deviren, MD; International Spine Study Group

IMAST 2013

Vancouver, British Columbia

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RESULTS

	OPEN	MIS	p value =
n	118	46	
Age (yrs)	60.6	64.1	0.022 (*)
Preop NSR Back	7.0	6.4	0.109
Preop NSR Leg	4.2	4.6	0.564
Preop ODI	41.4	42.7	0.624
Postop NSR Back	3.3	3.2	0.744
Postop NSR Leg	2.3	2.4	0.872
Postop ODI	25.1	23.7	0.653
Diff ODI	15.6	17.7	0.504

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Results

	OPEN	MIS	p value =
n	118	46	
Thoracic Kyphosis	33	31.9	0.707
Cobb-lumbar (°)	42.8	32.4	0.0001 (*)
SVA (cm)	5.8	3.4	0.03 (*)
LL (°)	41.1	34.4	0.033 (*)
PI-LL mismatch (°)	13.6	21.4	0.014 (*)
PT (°)	23.6	27.7	0.024 (*)

* = p < 0.05

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Conclusions

- Profile of ASD patients undergoing MIS correction
  - Less severe Cobb
  - Less severe global sagittal malalignment
  - Worse spinopelvic parameters (PT, PI-LL)
  - MIS patients tend to be older
- Greater PI-LL mismatch in MIS patients (increased lumbopelvic compensation in MIS patients?)
- Prospective, randomized trials necessary
- Other factors—BMI, EBL, revisions, complexity of deformities, complications, etc.

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CORONAL

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SPINE Volume 35, Number 26S, pp S312–S321
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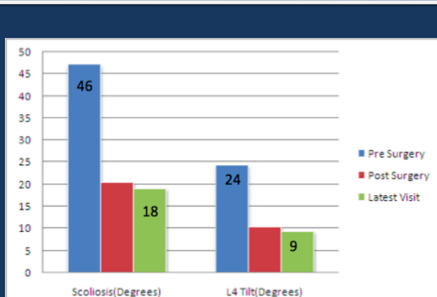
Adult Deformity Correction Through Minimally Invasive Lateral Approach Techniques

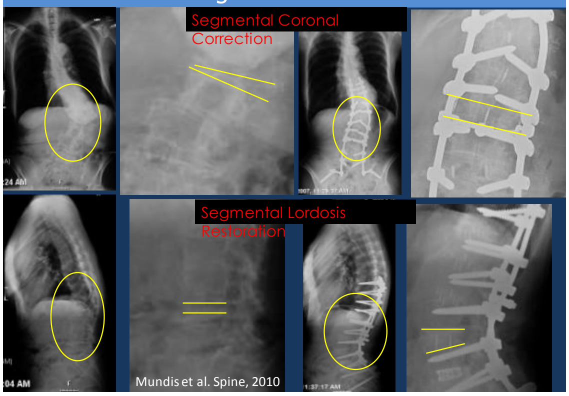
Gregory M. Mundis, MD,* Behrooz A. Akbarnia, MD,*† and Frank M. Phillips, MD‡

- 16 patients with minimum 2 year follow up
- All with VAS, ODI, and SRS-22 improvement
- All with LIF and open posterior

CORONAL CORRECTION LIF



LIF Segmental Correction



Acosta et. al

- 36 patients (66 levels)
- 7 with scoliosis
- 21.4 → 9.7 degrees ($p<0.05$)
- VAS and ODI both significantly improved

J Neurosurg Spine 15:92–96, 2011

Acosta et. al.

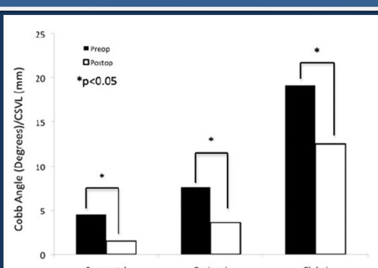


Fig. 2. Bar graph showing changes in coronal plane alignment after DLIF. The *left and center bars* show the segmental and regional Cobb angles, respectively. The *right bars* represent the center sacral vertebral line (CSVL).

J Neurosurg Spine 15:92–96, 2011

How does MIS compare to OPEN

A Prospective Propensity Matched Cohort Analysis of Minimally Invasive (MIS), Hybrid (HYB), and Open Spine Surgery (OPEN) for the Treatment of Adult Spinal Deformity (ASD)

Gregory M. Mundis, Jr., Virginie Lafage, Behrooz Akbarnia, Robert Eastlack, Michael Wang, Juan Uribe, Neel Anand, Praveen Mummaneni, David Okonkwo, Adam Kanter, Frank La Marca, Richard Fessler, Chris Shaffrey, Vedat Deviren, ISSG

- Propensity matched data by age, ODI, SVA and major Cobb
- 31 Open; 31 Hybrid; 31 MIS
- NO difference in Cobb correction between 3 groups

IMAST Vancouver 2013, Podium Presentation

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Is there a ceiling effect to MIS?

Wang et al. IMAST 2013

- 85 patients evaluated with 3 different techniques
  - Stand alone lateral, circumferencial MIS, Hybrid
- Stand alone 23 degrees
- Circumferencial: 34 degrees
- Hybrid: 50 degrees

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Comparison of 3 Minimally Invasive Surgery (MIS) Strategies to Treat Adult Spinal Deformity (ASD)

	Major Cobb	SVA	PI-LL	LL
OVERALL (n=99)	38→15	4.9→3.1	23→11	33→44
HYBRID (n=51)	44→17	6.7→3.2	22→3	32→48
SaMIS (n=8)	33→31	4.2→4.8	23→13.5	32→38.5
cMIS (n=40)	32→10	2.9→2.9	21→16	34→40

*ODI and VAS significantly improved in all 3 groups.

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SAGITTAL

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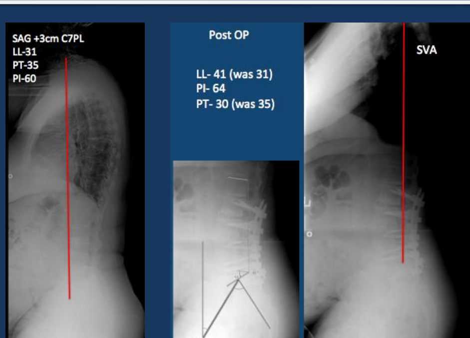
AN EVOLVING MIS FRONTIER

- Historically poor showing
- WHY?
  - Ignorance?
  - Surgeon planning error?
  - Implant limitations?
  - Technique limitations?
  - Education/training error?

INCOMPLETE CORRECTION



Regional Improvement

- 2… pts: LL imp… from 37 → 47.5
  - Wang … 201…
- 35 pts: LL im… → 46
  - Acosta et a…
- 8 pts … 47
  - …rmenti … al.
- 16 p… 1
  - …ia et al.

10.5 degrees

4… degrees

7 degrees

13 degrees

WHAT IS THE CORRECT QUESTION?

- Global Alignment?
- Regional Alignment?
- Segmental Alignment?

- What about Surgeon Goals?

Comparison of Radiographic Results after Minimally Invasive, Hybrid and Open Surgery for Adult Spinal Deformity: A multicenter Study of 184 patients

*Raqeeb Haque, Gregory M. Mundis Jr., Yousef Ahmed, Tarek Y. El Ahmadieh, Michael Wang, Praveen Mummaneni, Juan Uribe, David Okonkwo, Robert Eastlack, Neel Anand, Adam Kanter, Frank LaMarca, Behrooz Akbarnia, Paul Park, Virginie Lafage, Jamie Terran, Christopher Shaffrey, Eric Klineberg, Vedat Deviren, Richard G. Fessler, **ISSG***

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METHODS

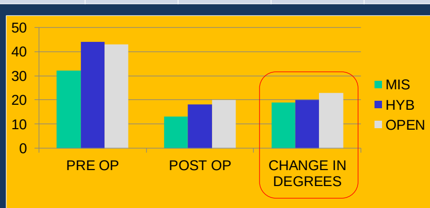
- Retrospective review of prospectively collected databases
- Inclusion criteria:
  - Age $\geq$ 45yrs
  - Lumbar Cobb $\geq$ 20 degrees
  - Minimum 1 year f/u

METHODS

- OPEN
  - Open correction of scoliosis using posterior technique for osteotomy and instrumentation
- MIS
  - Combination of LLIF/TLIF/facet fusion with percutaneous posterior instrumentation
- HYB
  - Combination LLIF/TLIF with OPEN posterior instrumentation

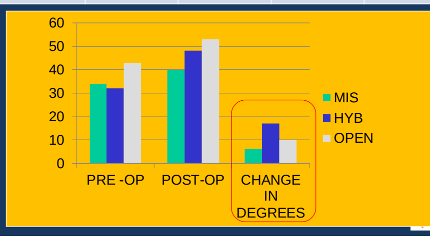
RESULTS

		MIS	HYB	OPEN
	PRE-OP	32.1*	44.3	43.2
COBB ANGLE	POST-OP	13.1*	17.7	20.4
	Δ	18.8	26.6*	22.8



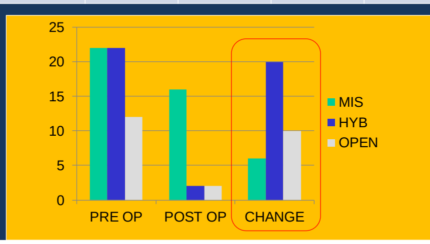
RESULTS

		MIS	HYB	OPEN
	PRE-OP	33.8	31.9	42.7
LORDOSIS	POST-OP	39.4	48.5	53.2
	Δ	5.8	17.4*	10.5



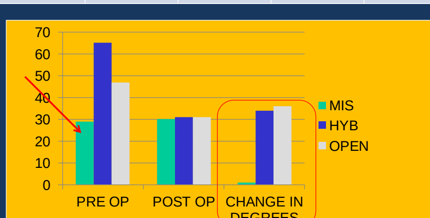
RESULTS

		MIS	HYB	OPEN
	PRE-OP	21.6	22.0	12.3
PI-LL	POST-OP	16.1	2.1	2.0
	Δ	5.5	20.6*	10.2



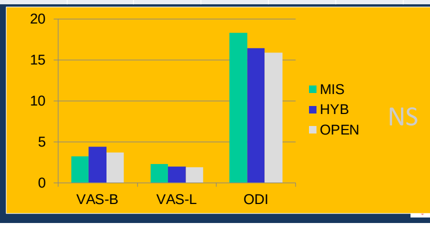
RESULTS

		MIS	HYB	OPEN
	PRE-OP	29	65	47
SVA	POST-OP	30	31	31
	Δ	1*	34	36



RESULTS

		MIS		HYB		OPEN	
		MEAN	SD	MEAN	SD	MEAN	SD
Δ	VAS-B	-3.2	2.1	-4.4	3.3	-3.7	3.0
PRE to	VAS-L	-2.3	3.8	-2.0	3.9	-1.9	3.8
POST	ODI	-18.3	17.0	-16.4	13.9	-15.9	17.4



WHAT IF YOU NEED MORE?

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Anterior Column Realignment (ACR) for Focal Kyphotic Spinal Deformity Using a Lateral Transpsoas Approach and ALL Release

Behrooz A. Akbarnia, MD,† Gregory M. Mundis, Jr, MD,* Payam Moazzaz, MD,* Nima Kabirian, MD,* Ramin Bagheri, MD,* Robert K. Eastlack, MD,‡ and Jeff B. Pawelek, BS**

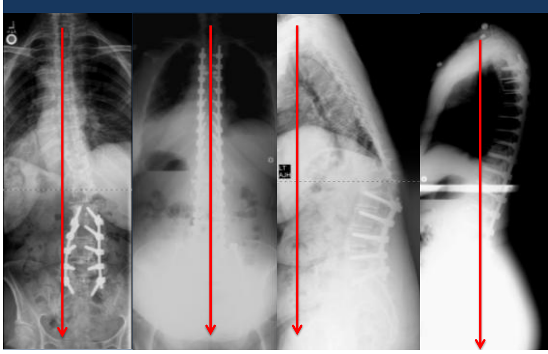
- 17 consecutive pts
- 24 mo f/u
- 14 with previous spine surgery
- 71% treated for ASD
- All had open posterior fusion
- 15/17 had a posterior release at the level of the ACR

JSDT 2013

Anterior Column Realignment (ACR) for Focal Kyphotic Spinal Deformity Using a Lateral Transpsoas Approach and ALL Release

- T1SPI:
  - -6 to -2 ($p<0.05$)
- LL:
  - 16 → 38 (ACR) → 45 after PSFI
- PT:
  - 34 → 24 (ACR)
- SRS-22, VAS improved pre → post ($p<0.05$)
- 8/17 complications
- 4 ACR related
  - 2 neurologic
  - 1 vascular (approach surgeon removing lateral plate)

72 YO F PJK S/P L1-S1



DOES IT COMPARE TO PSO?

Anterior Column Realignment (ACR) has Similar Results to Pedicle Subtraction Osteotomy (PSO) in Treating Adults with Sagittal Spinal Deformity: A Multicenter Study

Gregory M. Mundis, Jr., Behrooz A. Akbarnia, Nima Kabirian, Jeff Pawelek, Robert K. Eastlack, Chris Shaffrey, Eric Klineberg, Shay Bess, Chris Ames, Vedat Deviren, Virginie Lafage, ISSG

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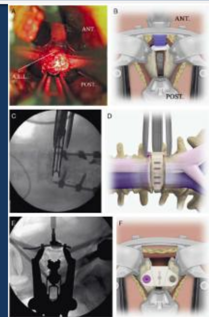
ACR v PSO

- PROPENSITY MATCHED
  - PI, LL, TK
- 17 patients in each group
- KEY FINDINGS:
  - Groups comparable
  - PSO with better T1SPI correction (SVA)
  - ACR with improved PT correction but no PSO
  - No difference in complication rate
  - ACR with less EBL



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HOW ABOUT COMPLICATIONS? PJK?

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Does Minimally Invasive Posterior Instrumentation (PPI) Prevent Proximal Junctional Kyphosis (PJK) in Adult Spinal Deformity (ASD) Surgery? A Prospectively Acquired Propensity Matched Cohort Analysis

Praveen Mummaneni, Michael Wang, Virginie Lafage, Kai-Ming Fu, John Ziewacz, Jamie Terran, David Okonkwo, Juan Uribe, Neel Anand, Richard Fessler, Adam Kanter, Frank LaMarca, Christopher Shaffrey, Vedat Deviren, Gregory Mundis, ISSG

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RESULTS

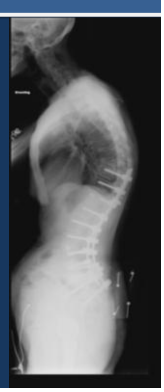
- 31 patients propensity matched in each group (CMIS, Hybrid)
- No significant difference in Age (65.6 vs 63.5, P=0.6)
- No significant difference in ASA score (1.8 vs 2.3 P=0.05)
- CMIS patients had lower ODI and VAS back pain scores but similar leg pain scores
  - ODI: 39.1 vs 48.1 (P=0.045)
  - VAS back: 6.1 vs 7.4 (P=0.013)
  - VAS leg: 4.1 vs 4.6 (P=0.53)

POST OP RESULTS

	CMIS		HYB		T-test
	Mean	SD	Mean	SD	P
Maximum Coronal Cobb	31.3	11.1	45.3	19.0	.001
Thoracic Kyphosis	31.1	10.0	30.4	16.6	.849
Lumbar Lordosis	32.7	11.5	34.8	17.5	.593
Pelvic Tilt	25.9	11.8	27.4	11.1	.597
Pelvic Incidence	52.6	13.9	55.4	12.2	.389
Sagittal Vertical Axis	29.2	41.7	53.3	61.4	.076
PI-LL	19.8	11.7	20.7	21.4	.845

PJK RESULTS

- Junctional segment analysis revealed that CMIS had a smaller change in PJA (1.3degrees vs 6 degrees, P=0.005)
- PJK developed in 19.4% of patients in the hybrid group by 1 year
- No PJK was detected at 1 year in the CMIS group.



CONCLUSION

- CMIS and Hybrid approaches resulted in similar sagittal plane radiographic and in HRQL results
- Radiographic PJK was detected in fewer patients in the CMIS group at 1 year
- PPI may provide benefit in reducing PJK in adult deformity procedures

Are Complications in Adult Spinal Deformity (ASD) Surgery Related to Approach or Patient Characteristics?

A Prospective Propensity Matched Cohort Analysis of Minimally Invasive (MIS), Hybrid (HYB), and Open (OPEN) Approaches

Juan S. Uribe, Praveen Mummaneni, Gregory Mundis, Virginie Lafage, Behrooz Akbarnia, Paul Park, Robert Eastlack, Michael Wang, Neel Anand, David Okonkwo, Adam Kanter, Frank La Marca, Vedat Deviren, Richard Fessler, Chris Shaffrey, ISSG

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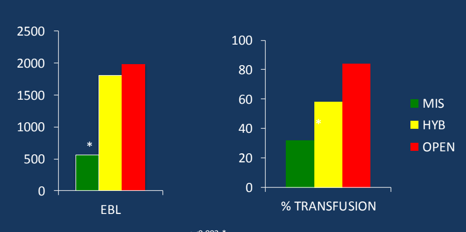
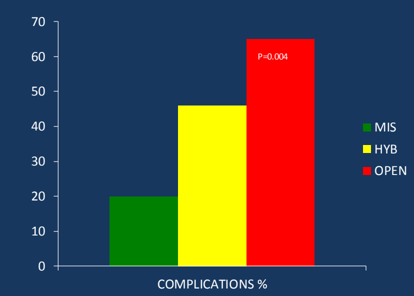
OPERATIVE DATA



p<0.003 *

TOTAL COMPLICATIONS



COMPLICATIONS

Complication	MIS	HYB	OPEN	Total	Chi
With any	**20%**	**46%**	**65%**	**45.2%**	**0.004**
Intraoperative		16.7%	27.6%	15.5%	0.020
Postoperative	20%	36.7%	55.2%	38.1%	0.029
Major	12%	33.3%	44.8%	31%	0.032
Minor	8%	33.3%	41.4%	28.6%	0.020
DVT		10%		3.6%	0.061
PE		6.7%	3.4%	3.6%	0.414
Implant failure	8%	3.3%	6.9%	6%	0.740
Neuro deficit		13.3%	3.4%	6%	0.090
Pneumonia		3.3%		1.2%	0.402
Wound dehiscence		3.3%		1.2%	0.402
Wound infection		3.3%	3.4%	2.4%	0.648
PJK		3.3%	3.4%	2.4%	0.648
Other major		6.7%	34.5%	14.3%	0.000

CONCLUSION

- The surgical approach did matter when evaluating for complications
- The MIS group had significantly fewer complications (P=0.004) than did the HYB group or the OPEN group
- If the goals of ASD surgery can be achieved, consideration should be given to less invasive techniques in order to reduce complications.

SUMMARY

- MIS Spine surgery for deformity has it's limitations
  - Surgeon technique
  - Unknown fusion rates
  - Severity of deformity
- The present and potential benefits warrant further investigation
  - The inventors and early adopters should be encouraged to continue to drive the market to see if they can cross the chasm

THANK YOU

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Health Economic Analysis of Adult Spinal Deformity

Ian McCarthy, PhD
Institute for Health Care Research and Improvement
Baylor Health Care System
Baylor Scoliosis Center

Southern Methodist University
Department of Economics

VuMedi Webinar
August 2013

Role of Health Economics in Spine Surgery

- Patterns and determinants of health care utilization and production
- Impact and calculation of alternative reimbursement models
- Studies of market structure
- Health care labor markets
- **Assessing the value of surgical treatment**

Measuring Value

- **Outcomes:** Survival, readmissions, complications, health-related quality-of-life (HRQOL), quality-adjusted life-years (QALYs)
- **Costs:** Indirect vs direct, sometimes difficult to measure
- **Methods of analysis:** Decision analysis, incremental cost-effectiveness, comparative-effectiveness

Quality-of-Life Outcomes

- Measuring quality of life
  - Generic health profiles: SF-36, EQ-5D, Health Utilities Index (HUI)
  - Disease specific questionnaires: ODI, SRS-22
  - Utility-based quality-of-life for estimation of quality-adjusted life-years (QALYs): SF-6D, EQ-5D, HUI

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QALYs

- QALYs are fundamentally grounded in economic theory and expected utility theory in particular…cannot be estimated from every HRQOL questionnaire
- Collapses HRQOL profiles over time into a single number
- Each year of life is weighted by the "quality" of that year, with the quality factor derived by applying the relevant scoring algorithm to the HRQOL responses
- Quality factor generally ranges from 0 to 1, with 1 representing perfect health and 0 representing death
  - Values < 0 are also possible
- Two years of life at a quality of 0.5 yields 1 QALY

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Estimating QALYs in ASD

- Clear selection issues into surgery, making comparisons between operative and non-operative patients empirically difficult
- Many patients have lived with condition for years and may not present particularly poor baseline HRQOL
- Difficult to quantify the reduction in HRQOL that would have happened without surgical intervention
  - Relates to argument that surgery should be pursued earlier while patient can appropriately recover. Need evidence-based justifications for this approach (how much would HRQOL deteriorate without surgery?)

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Defining Costs

Direct Costs: Resources consumed for the care of the patient.

Indirect Costs/Benefits: Time of patients or families consumed or freed by the program in question.

Some confusion as the term "indirect costs" is used in accounting to denote overhead. For economic evaluation of health care programs, overhead is generally considered part of the direct cost of care, although the allocation of overhead to a specific surgery will tend to differ across hospitals.

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Measuring Costs

- Hospital Costs
  - Direct costs of patient care plus overhead and operational costs. Many studies unclear as to whether overhead/operational costs are included in calculation.
  - High quality data but difficult to access for most authors.
- Payments/ Reimbursements
  - Medicare formulas easy to replicate, but will differ dramatically from managed care payments
  - Very difficult or expensive to access managed care claims data
- Charges
  - Poor measure of costs or reimbursements (monopoly money)
  - Cost to charge ratios can be used for adjustments. Should be performed at service level and not simply at hospital level.

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Sources of Data

- Hospital Costs
  - Accessed from hospital accounting records. Often unclear as to whether costs include overhead or operational costs.
  - In many states, hospital costs will exclude surgeon, anesthesiologist, and internist fees (anyone who is not an employee of the hospital).
  - Excludes follow-up costs (rehab, prescription drugs, outpatient visits)
- Payments/ Reimbursements
  - Medicare inpatient reimbursement rates by DRG available from MedPAR, and physician fees can be estimated from CPT codes
  - Actual Medicare claims available from CMS
  - Managed care claims potentially available from HCCI and MarketScan Claims database (expensive)
- Charges
  - Department level cost to charge adjustments can be estimated from publically available HCUP data.

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Current Research: Costs of ASD

Aggregate Data from NIS (Healthcare Cost and Utilization Project)

- Inpatient stays in 2010
  - 20,600 based on principal diagnosis
  - 223,000 including secondary diagnoses
- Cost per inpatient stay
  - $56,000 (3x more expensive than all other spine diagnoses)
- Annual costs
  - $4.5 billion including secondary diagnoses
  - Underestimate due to readmissions, rehab, prescription drugs, and indirect costs

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Current Research: Costs of ASD

Current Literature

- Average cost of $77,432 for revision surgery following proximal junctional failure (Hart et al., 2008)
- Total hospital costs average $120,000 including subsequent readmissions, with reimbursements averaging $200,000 (BSC Data)
  - $100,000 per-patient for primary surgery ($70,000 - $80,000 excluding hospital overhead)
  - $70,000 per-patient for readmissions
- Implant costs average $40,000 and account for 40% of total hospital costs on average (BSC Data)
- No current studies of follow-up or indirect costs

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Current Research: Costs of ASD

Why Does it Matter

- Measure of costs will dramatically change conclusions on CE of surgery
- Hospital costs of $120,000 versus reimbursements of $200,000 (including readmissions)
  - CE much worse when using actual reimbursements rather than hospital costs
- Primary surgery costs of $100,000, increases to over $120,000 on average per patient after accounting for readmissions
  - 20% reduction in CE
- Rehab and prescription drug costs likely to be significant, in addition to indirect costs

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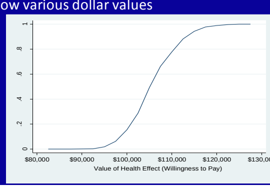
Cost-effectiveness

- Cost-effectiveness analysis is generally considered to be an incremental analysis…need to compare one treatment to another
- Most common measure of incremental cost-effectiveness:

$$ICER = \frac{\text{Operative Costs} - \text{Non-operative Costs}}{\text{Operative QALYs} - \text{Non-operative QALYs}}$$

Cost-Effectiveness Analysis

- Statistical analysis of ICERs is difficult since denominator may = 0 and sign of ratio may be uninformative
- Common presentation of results:
  - ICER and 95% confidence interval
    - Standard confidence interval formulae are not appropriate
    - Confidence interval calculated based on alternative formula or bootstrap technique
  - Cost-effectiveness Acceptability Curves (CEAC): probability of ICER falling below various dollar values



Current Cost-Effectiveness

<u>Worst Case</u>

- Across ISSG centers, average baseline SF-6D ranges from 0.47 to 0.68. Two-year follow-up ranges from 0.58 to 0.78
- Average gain of 0.16 QALYs after two-years, projected 0.4 QALYs after 5 years
- At $200,000 in reimbursements over 5-yr period, incremental CE is **$500,000 per QALY** (excluding rehab and prescription drugs)

<u>Best Case</u>

- Predicted QALYs gained = 0.7 after 5 years
- At $200,000 in reimbursements over 5-yr period, incremental CE still exceeds **$280,000 per QALY** (excluding rehab and prescription drugs)

Even with a high CE threshold of $140,000 (World Health Organization recommendation of 3x per-capita GDP), ASD surgery is not cost-effective without more formal empirical analysis and extended or projected follow-up

How to Improve CE Results?

1. Need to appropriately quantify hypothetical QALYs without surgery
2. Investigate cost drivers
   - Most costs incurred at index, but readmissions play important role both by increasing costs and decreasing incremental QALYs
   - Implants are biggest single category of cost drivers…a 10% reduction in implant costs is equivalent to a 13% reduction in readmissions
   - Potential conflicting incentives for cost reduction in states where managed care remains a cost-plus reimbursement system
3. Prolonged evaluation period
   - Assess long-term durability of ASD surgery
   - Surgery begins to look cost-effective at 10+ years
4. Selection of surgical patients
   - Baseline HRQOL is perhaps the most relevant predictor of future cost-effectiveness…many patients report similar post-operative HRQOL values, so baseline values are biggest differentiating factor

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Thank You

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