# Is There Value In Surgery For Adult Spinal Deformity?

Shay Bess, MD
Denver International Spine Center
Denver, CO

***Selby Spine Conference***
***February 2018***
***Park City, UT***

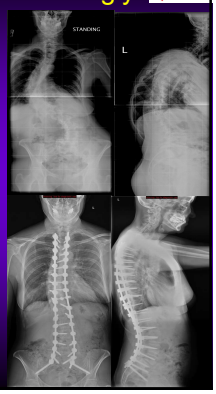
## Disclosures Shay Bess

- Consulting= Allosource, K2M
- Royalties= Pioneer Spine, K2M
- Research support= Depuy/Synthes, EOS Medtronic, K2M, Nuvasive, Orthofix, Globus
- Scientific advisory board= Allosource

## Value In Surgery For ASD

## Value ASD Surgery= Bad and Ugly

- ASD surgery expensive
  - McCarthy, ISSG TSJ 2014
  - Mean 4.8 years f/u (n=415)
- Bad
  - Mean total hospital costs= $120,394
  - Primary ASD surgery=$103,143
  - OR costs=$70,514 (59% costs)
  - CMS reimbursable= $65,000 (54%)
- Ugly
  - Readmissions (29%)= $67,262
  - Complications
  - Smith, ISSG JNS 2017=78% 3CO
  - Sorocenau ISSG Spine 2015= 31% implant; 52% treated surgically
  - Sorocenau ISSG Spine 2015= 27% minimum 1 medical complication




## Value ASD Surgery= Do Bad and Ugly Win?

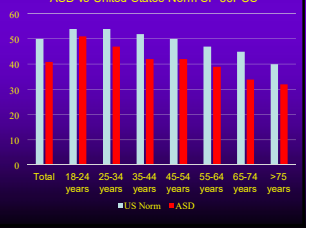
- Value
  - the monetary worth of (something):
  - the importance, worth, or usefulness of something
- Questions
  - Is ASD important?
  - Are there treatment alternatives?
  - Do alternatives work?
  - Can we improve on current state? Variance
    - McCarthy, ISSG TSJ 2014
    - Physician preference=largest determinant OR costs


## Is ASD Important?

- ISSG Spine 2016
- Quantify ASD disease impact
  - ASD cohort (n=497)
  - No prior surgery
- ASD SF-36 PCS, MCS
  - Population norm
  - Generational norms
  - Chronic disease
- ASD vs. U.S. generational norms: PCS
  - <25th percentile all generations
  - More rapid decline than U.S. general

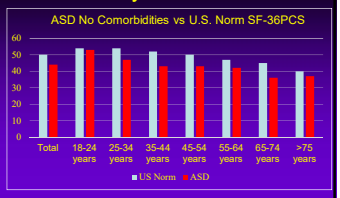

Spine

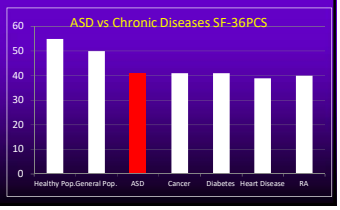
The Health Impact of Symptomatic Adult Spinal Deformity: Comparison of Deformity Types to United States Population Norms and Chronic Diseases



## ASD and Disability

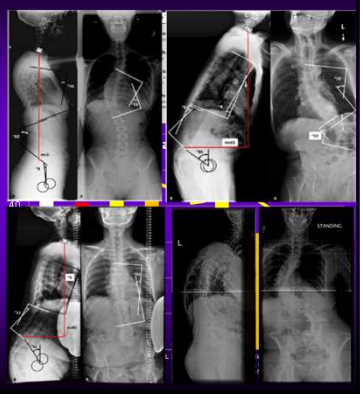
- ASD no other comorbidities vs U.S.
  - <25th percentile
  - All ASD generations (except 18-24 yr)
  - More rapid decline than U.S. general
- ASD vs. US Healthy and Disease Norms
  - >1 MCID back pain/sciatica
  - >1 MCID Hypertension
- Similar
  - Cancer
  - Diabetes
  - Heart disease



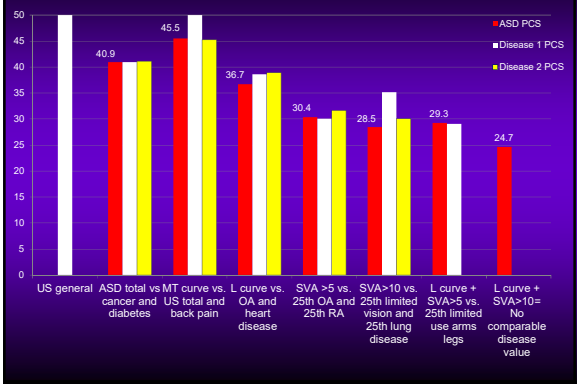




## ASD Deformity Type and Disability

- ASD heterogenous
  - Type (sagittal, coronal, mixed)
  - Location (thoracic, lumbar, etc)
  - Severity
- Cohort division SRS-Schwab Classification
- PCS worsens
  - Curve location
  - Sagittal malalignment



## ASD Type, Severity and Disease Correlates



## What Are Treatment Solutions ASD?

- Does nonoperative treatment work?
- Depends on severity; but not really
- Bridwell, SDSG Spine 2009
  - Op= improved all HRQOL (95% f/u)
  - Non= no change HRQOL (45% f/u)
- Smith, ISSG Neurosurg 2015
  - Op= improved all HRQOL (85% f/u)
  - Non= no change HRQOL (55% f/u)
- Glassman, SDSG Spine 2010
  - No treatment= no change (satis)
  - Nonoperative resources= no change
  - Treatment costs; mean= $10,815
    - Low symptom=$9704
    - Mild symptom= $11,116
    - High symptom= $14,022


Does Treatment (Nonoperative and Operative) Improve the Two-Year Quality of Life in Patients With Adult Symptomatic Lumbar Scoliosis

Outcomes of Operative and Nonoperative Treatment for Adult Spinal Deformity: A Prospective, Multicenter, Propensity-Matched Cohort Assessment With Minimum 2-Year Follow-up

The Costs and Benefits of Nonoperative Management for Adult Scoliosis

Table 5. Mean Costs at Year 1 and Year 2 for the 3 Different Symptom Groups

| | ODI ≤20 | ODI 21–40 | ODI >40 | Entire Cohort |
|---|---|---|---|---|
| Cost Year One ($) | 4160.46 | 4580.05 | 5739.15 | 4417.97 |
| Cost Year Two ($) | 5543.81 | 6636.31 | 8282.89 | 6298.81 |
| Cost Total ($) | 9704.27 | 11,116.36 | 14,022.04 | 10,814.78 |

## How Much Will I Improve After My Surgery and Will I Be Normal? The Critical Importance of Collecting and Discussing Patient Reported Outcomes Measures (PROMs) With Adult Spinal Deformity (ASD) Patients

Shay Bess MD, Breton Line BS, Virginie Lafage PhD, Frank Schwab MD, Renaud Lafage MS, Christopher Ames MD, Douglas Burton MD, Munish Gupta MD, Han Jo Kim MD, Michael Kelly MD, Robert Hart MD, Eric Klineberg MD, Khaled Kebaish MD, Richard Hostin MD, Gregory Mundis MD, Christopher Shaffrey MD, Justin S. Smith MD, PhD, International Spine Study Group

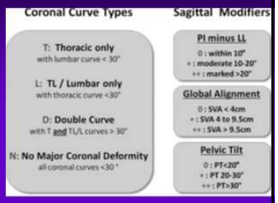
*52nd Annual Meeting Scoliosis Research Society*
Philadelphia, PA
August 2017

## Study Question and Purpose

- Baseline disability dependent ASD
  - Type and severity
- Surgical improvement dependent ASD?
  - Type and severity
- Multi-center, prospective ASD database
- Different spine deformity types
  - SRS-Schwab ASD Classification
- Quantify postoperative percentage improvement
  - Back and leg pain
  - Self-image
  - Physical and social function
  - Mental health
- Assess return to generational norms
- PROM domains most impacted

## Materials and Methods

- Data source
  - ISSG database
  - Multi-center, prospective, ASD
- Database inclusion criteria
  - Age >18 years
  - Minimum one: scoliosis >20°, SVA >5cm, PT>25°, TK >60°
- Study inclusion criteria
  - Surgery for ASD
  - PSF ≥4 levels
  - Minimum two year follow-up
- ASD type
  - SRS-Schwab ASD Classification



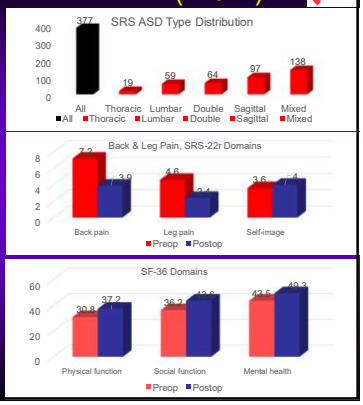

## Materials and Methods

- Percent change ASD type
- Preoperative vs. last follow up
  - NRS back and leg pain
  - Specific domains
    - SF-36
    - SRS-22r
- Domains >1 SD generational norm
  - Most impacted domains
  - Return to "normal"

| PROM Domains |
|---|
| SF-36 |
| Physical function |
| Bodily pain |
| Role physical |
| General health |
| Vitality |
| Social function |
| Role emotional |
| Mental health |
| SRS-22r |
| Pain |
| Activity |
| Appearance |
| Mental health |

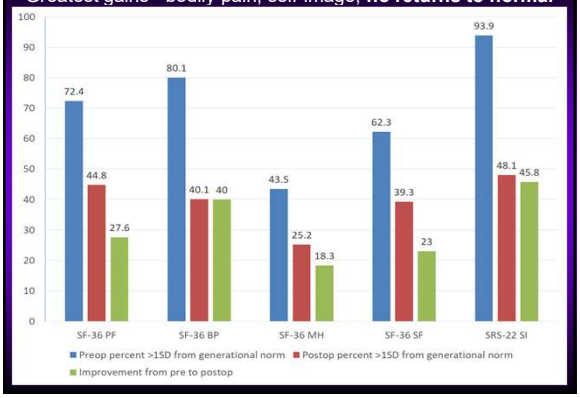
## Results: All ASD Patients (n=377)

- All ASD
  - N= 377/582 (65%)
  - Age 57.8 years
  - ASA grade= 2.4
  - Scoliosis= 42.6°
  - SVA= 63.9mm
  - PSF= 11.7 levels
- Pain improvement
  - Back= 44%
  - Leg= 39%
- Self-image= 61%
- Function improvement
  - Physical= 30%
  - Social= 35%



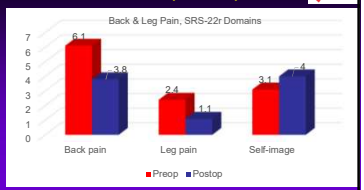
## Results: All ASD vs. Generational Norm

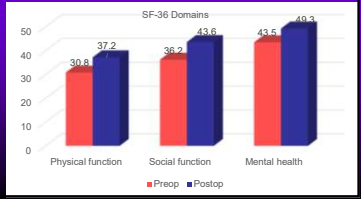
Greatest gains= bodily pain, self-image; **no returns to normal**




## Results: Thoracic ASD (n=19)

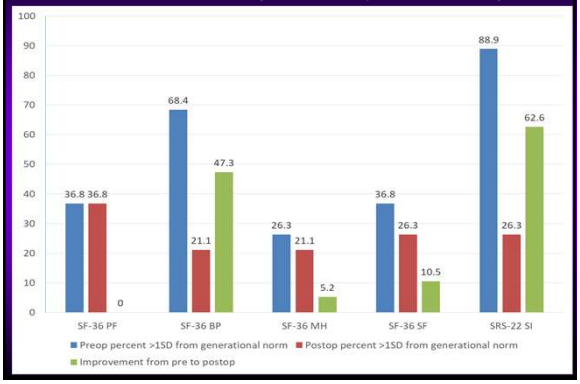
- Thoracic ASD
  - Age 33.1 years
  - ASA grade= 1.7
  - Scoliosis= 47.1°
  - PSF= 11.3 levels
- Pain improvement
  - Back= 34%
  - Leg= 46%
- Self-image= 36%
- Function improvement
  - Physical= 18%
  - Social= 15%
  - Mental= 17%



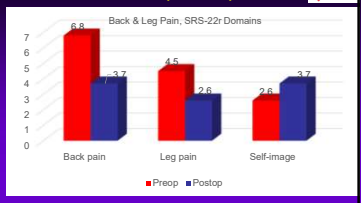

## Results: Thoracic ASD vs. Generational Norm

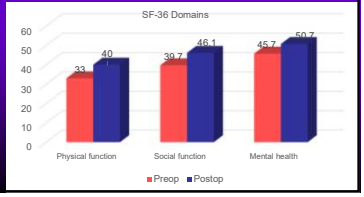
Best return to norm all groups; bodily pain, self-image



## Results: Lumbar ASD (n=59)

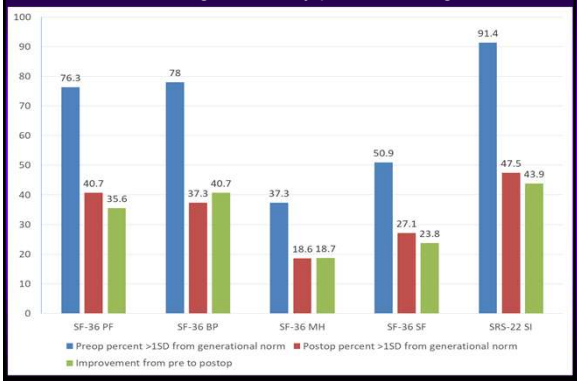
- Lumbar ASD
  - Age 55.6 years
  - ASA grade= 2.2
  - Scoliosis= 41.4°
  - PSF= 10.7 levels
- Pain improvement
  - Back= 47%
  - Leg= 42%
- Function improvement
  - Physical= 27%
  - Social= 32%
  - Mental= 20%
- Self-image= 58%



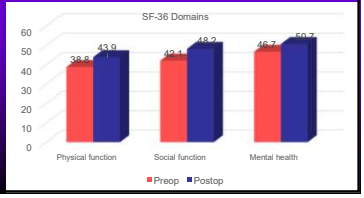

## Results: Lumbar ASD Generational Norm

Greatest gains; bodily pain, self image

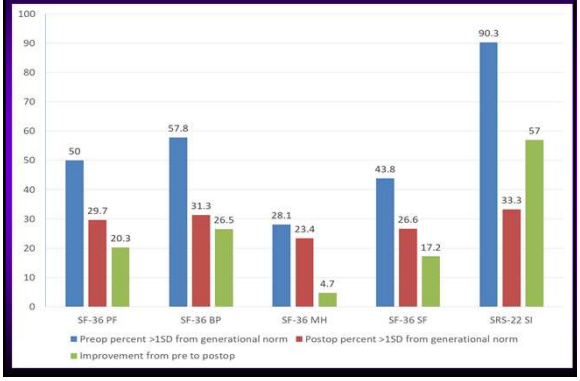



## Results: Double ASD (n=64)

- Double ASD
  - Age 48.5 years
  - ASA grade= 2.1
  - Scoliosis= 62.3°
  - PSF= 12.7 levels
- Pain improvement
  - Back= 34%
  - Leg= 23%
- Function improvement
  - Physical= 21%
  - Social= 27%
  - Mental= 18%
- Self-image= 58%

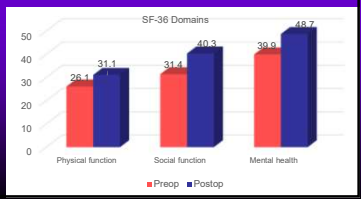



## Results: Double ASD Generational Norm
Greatest gains; self image

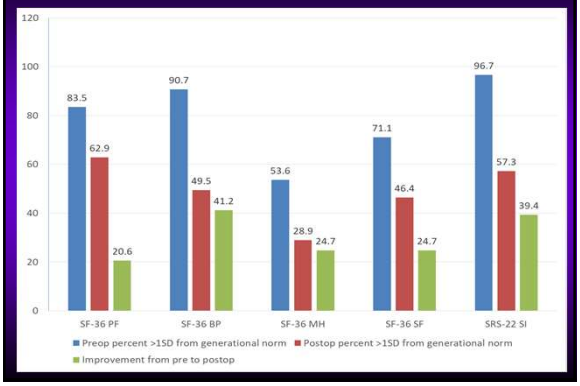



## Results: Sagittal ASD (n=97)

- Sagittal ASD
  - Age 62.9 years
  - ASA grade= 2.6
  - SVA= 109.3mm
  - Prior surgery= 77.3%
- Pain improvement
  - Back= 44%
  - Leg= 34%
- Function improvement
  - Physical= 44%
  - Social= 38%
  - Mental= 18%
- Self-image= 61%

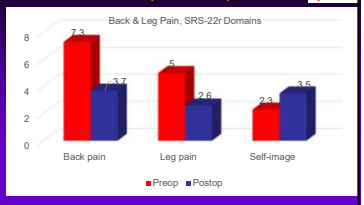



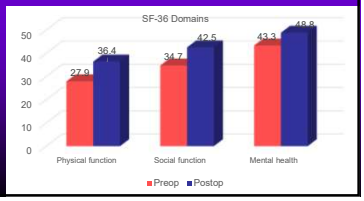

## Results: Sagittal ASD Generational Norm
Worst returns to "normal"



## Results: Mixed ASD (n=138)

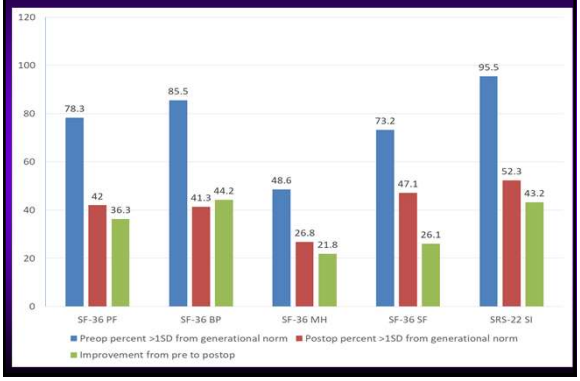
- Mixed ASD
  - Age 63 years
  - ASA grade= 2.5
  - Scoliosis= 48.8°
  - SVA= 103.7mm
- Pain improvement
  - Back= 49%
  - Leg= 48%
- Function improvement
  - Physical= 40%
  - Social= 40%
  - Mental= 22%
- Self-image= 68%



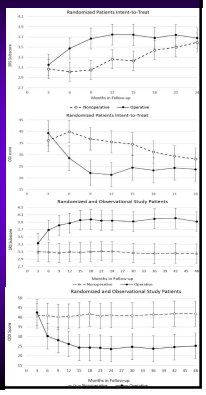

## Results: Mixed ASD Generational Norm

Second worst returns to "normal" (behind Sagittal cohort)




## Cost-Effectiveness ASD Treatment

- ASLS I Study (Bridwell, et al)
- Multi-Centered Prospective Trial
- Lumbar scoliosis >30 +
  - SRS-22r ≤ 4.0 (pain, function, self-image)
  - And/or ODI ≥ 20
- Randomized cohort (RC; n=63)
- Observational cohort (OB; n=223)
- 90% follow up 4yrs
- Results
  - Intent to treat: OP= NON (RC only)
  - As treated: OP>NON (RC+OB)
  - OP vs NON equivalent Incremental Cost Effectiveness Ratio (ICER) benefit at 2 years



## Cost-Effectiveness ASD Treatment

- ASLS I Study (Bridwell, et al)
- Incremental Cost Effectiveness Ratio (ICER) 2 years; OP =NON
- Operative group
  - mean total costs=$110,023 ($84,101 direct, $25,922 indirect)
  - QALY gain
    - ODI= 0.08 (SD 0.08)
    - SF-12= 0.10 (SD 0.12)
- NON group
  - mean total cost = $17,565 ($9,289 direct, $8,276 indirect)
  - QALY gain
    - ODI= 0.01 (SD 0.05)
    - SF-12=0.02 (SD 0.10)
- OP= greater benefit
- Cost/QALY gain equal

## Cost-Effectiveness ASD Treatment

- Problems ASLS I Study
- Impact of as treated analysis
- Crossovers (RC)
  - OP to NON=6
  - NON to OP= 23
  - Worse preop
  - Better postop
- Result
  - ASLS II not renewed by NIH
  - No difference OP vs NON

| | Randomized (n=63) | % Per Arm | Observational (n=223) | % Per Arm |
|---|---|---|---|---|
| Operative to Nonoperative | 6 | 20% | 0 | 0% |
| Nonoperative to Operative | 23 | 70% | 20 | 18% |
| Total | 29 | 46% | 20 | 9% |

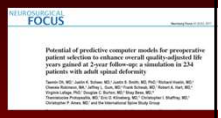
| Treatment Assigned | Operative (n=30) | | | Nonoperative (n=33) | | |
|---|---|---|---|---|---|---|
| Treatment Received | Operative (n=24) | Nonoperative (n=6) | p value | Nonoperative (n=10) | Operative (n=23) | p value |
| SRS-22r Subscore | 3.1 (0.5) | 3.3 (0.4) | 0.31 | 3.4 (0.5) | 2.9 (0.5) | 0.02 |
| ODI score | 33.7 (15.5) | 33.3 (14.1) | 0.92 | 30.2 (17.0) | 45.3 (14.3) | 0.02 |
| Sagital Balance (mm) | 32.2 (36.7) | 34.0 (32.3) | 0.63 | 23.1 (31.0) | 59.2 (44.8) | 0.02 |
| Age at Enrollment (yrs) | 59.5 (9.5) | 64.5 (8.2) | 0.19 | 62.7 (9.4) | 61.9 (9.6) | 0.89 |

## Cost-Effectiveness ASD Treatment

- Needs/aims ASLS II= 8-10 year f/u
- Continue OP vs NON ICER
  - Durability treatment
  - Revisions= drive down OP cost effectiveness
  - Adverse events= drive down OP cost effectiveness
  - Decline function OP vs NON
- Predictive modeling patient characteristics
  - Revisions
  - Adverse events
- Partnership
  - SRS and ISSG
  - 5 industry partners
  - ASLS II through completion

## Conclusions

- Value ASD surgery
- ASD important
  - Impactful quality of life
- Surgery
  - Improve HRQOL
- Nonoperative care
  - Minimal improvement
- ASD disability discrepant
  - Patient and deformity type
- Problem to resolve= variance
  - Operative costs; Implant and biologics
  - Outcomes
  - Complications
- Role of predictive analytics
  - Ames, ISSG, ESSG
  - Models 90% accuracy
  - MCID, QALY at 2 years, catastrophic direct cost (>100K)




Preoperative Prediction of Cost and Catastrophic Cost (CC) in Adult Spine Deformity (ASD) Surgery: Feasibility Analysis of Predictive Analytics to Establish 90 Day Bundled Payments

Miquel Serra, PhD, Michael Kelly, MD, Justin S. Smith, MD, PhD, Ferran Pellisé, MD, Ahmet Alanay, MD, Emre Acaroğlu, Javier Sánchez Pérez-Grueso, MD, Frank Kleinstück, MD, Ibrahim Obeid, MD, Samrat Yeramaneni, MBBS, PhD, Rick Hostin, MD, Jeffrey L. Gum, MD, Corinna C. Zygourakis, MD, Virginie Lafage, PhD, Frank Schwab, MD, Christopher I. Shaffrey, MD, Douglas Burton, MD, Shay Bess, MD, Christopher P. Ames, MD, ESSG, ISSG

## Thank You

Denver International Spine Center
Health ONE DISC Physician Care
Rocky Mountain Hospital For Children at PSL

ISSG INTERNATIONAL SPINE STUDY GROUP