Pain, Disability and Adult Spinal Deformity; Old Myths, New Findings and Efforts from International Spine Study Group

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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. JBJS 2000
• Results
  – LIS = more pain and cosmetic
  – LIS 68% = little or moderate pain
  – No effect on function, marital

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
  – Health impact vs. disease states
  – Preoperative planning
  – Complications

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<thead>
<tr>
<th>Site</th>
<th>Members</th>
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<tbody>
<tr>
<td>OHSC</td>
<td>Hart</td>
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<tr>
<td>UC Davis</td>
<td>Gupta, Klineberg</td>
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<td>UCSF</td>
<td>Alias, Dainir, Mummaneri</td>
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<td>San Diego</td>
<td>Alvarado, Mundy, Eastlack</td>
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<td>Colorado</td>
<td>Bass, Line</td>
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<td>Hostin, O’Brien, McCarthy</td>
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<td>HSS</td>
<td>Boachie, Kim</td>
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<td>NYU/HUD</td>
<td>Lalagi, Schwab</td>
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<td>Virginia</td>
<td>Shaffrey, Smith</td>
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</tbody>
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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

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


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

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

<table>
<thead>
<tr>
<th>Disease State</th>
<th>PCS: mean NBS points</th>
<th>MCS: mean NBS points</th>
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</thead>
<tbody>
<tr>
<td>US Total Population</td>
<td>50</td>
<td>49.9</td>
</tr>
<tr>
<td>US Healthy Population</td>
<td>55.4</td>
<td>52.9</td>
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<tr>
<td>ASD</td>
<td>46.9</td>
<td>49.4</td>
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<tr>
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<td>45.7</td>
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<tr>
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<td>47.6</td>
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<tr>
<td>Depression</td>
<td>45.4</td>
<td>36.3</td>
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<tr>
<td>Diabetes</td>
<td>41.1</td>
<td>47.9</td>
</tr>
<tr>
<td>Heart Disease</td>
<td>38.9</td>
<td>48.3</td>
</tr>
<tr>
<td>Hypertension</td>
<td>44.0</td>
<td>49.7</td>
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<tr>
<td>Limited Use Arms</td>
<td>39.0</td>
<td>43.0</td>
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data collection

- Demographic, radiographic, HRQOL
- ASD SF-36
  - Physical component score (PCS)
  - Mental component score (MCS)
  - Compared to United States (US)
  - Total population norms
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Results: ASD No Other Comorbidities

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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
      - Diabeties
      - Heart disease
      - Limited use arms or legs
      - Lung disease
Conclusions

- ASD = substantial disease impact
- SF-36 questionnaire/MCID values
  - ASD = 3 MCID values below U.S. general population
  - <25th percentile all generations except youngest
  - Greater generational worsening
- ASD vs. other disease states
  - Worse
    - Back pain/sciatica
    - Hypertension
  - Similar
    - Cancer, diabetes, heart & lung disease
- Future work
  - Dissemination: medical community & Federal funding sources
  - Health economics: cost effectiveness ASD vs. other disease states

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


20th International Meeting on Advanced Spine Technologies
Annual Meeting
Vancouver, Canada
July 2013

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; SV A>10=PCS lower ANY RECORDED VALUE!!

ASD Deformity Types:
- S123: Thoracic=2 MCID below General Population
- Sc123: Lumbar =5 MCID below General Population
- L curve + Severe SSM; SV A>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

Summary

- ISSG efforts and future direction
- Adult Spinal Deformity= disability
  - Parameters correlating with disability
  - Guidelines for evaluation
- ASD treatment
  - Demonstrate efficacy
  - Who benefits most
  - Risk factors for poor outcome
  - Alignment goals
- Complication analysis
  - Risk factors
  - Impact on outcome and cost
  - BMP use
- Cost effectiveness
  - Operative vs. nonoperative
  - Durability treatment

ASD: Operative vs. NonOperative Care

- Treatment choices ASD
  - ISSG, Spine 2009
    - Retrospective; 290 ASD
    - OP=NON: age, comorbidities
    - OP worse HRQOL
    - Surgical treatment
      - Youngest=scoliosis
      - Oldest= pain/disability
  - Fu,ISSG, SRS/NASS 2012
    - Prospective 497 ASD
    - OP worse HRQOL
    - Youngest OP=scoliosis
    - Oldest OP= SSM
Thank You