



Quality of Life Outcomes in Early Onset Scoliosis

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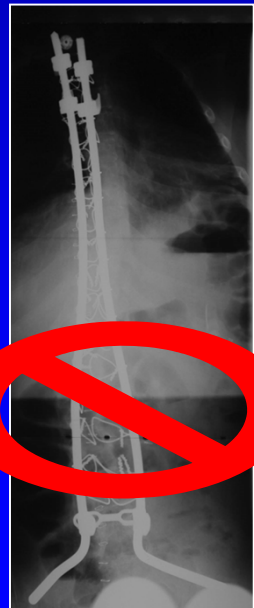
Why Assess Quality of Life ?

- Realization that “technical”, “traditional” endpoints have shortcomings
- Different, but better ?
- QOL may be the best endpoint to use when assessing the effect we have on our patients

Patient-Based Outcomes

- “In the field of scoliosis, there is one rule: keep your eye upon the patient, and not upon the curve.”
-Cobb, 1948

- “Treat the patient, not the x-rays.”
- Blount, 1955



OUTCOMES:

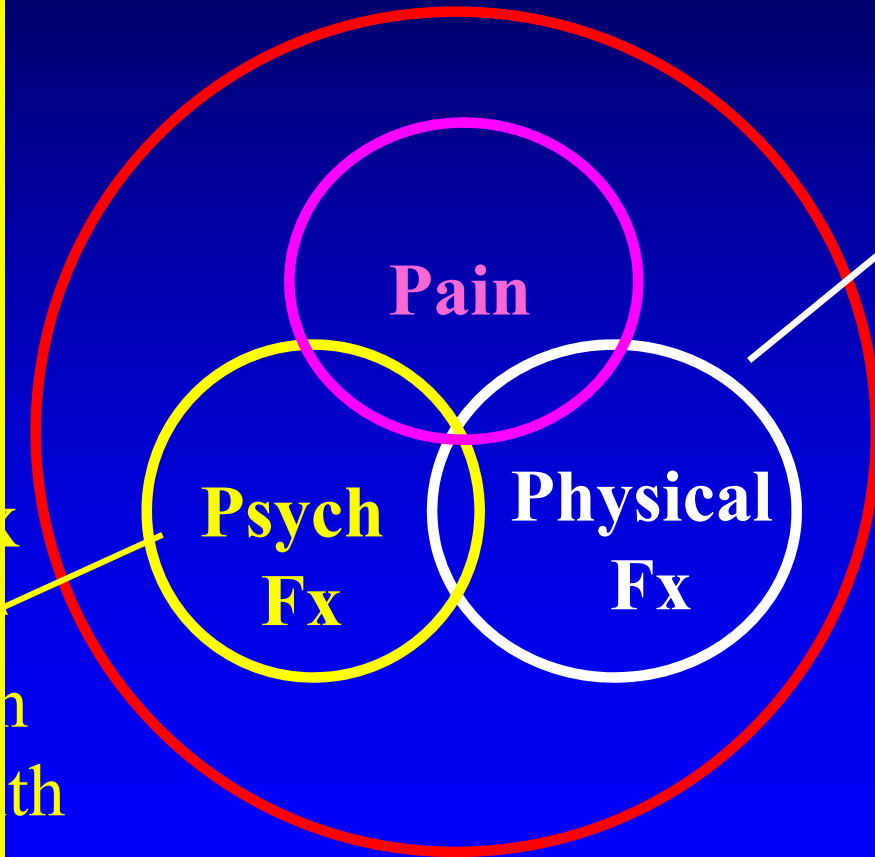
Why Treat Children With Scoliosis?

- To decrease curve/stop progression curve...
 - decrease pain or increase function ?
 - for psychosocial reasons ?
 - for cosmetic reasons/self image ?
 - To improve lung function ?
- To prevent *future* progression and *future* disability
- Will QOL measures respond to any of the above?

“Quality of Life”



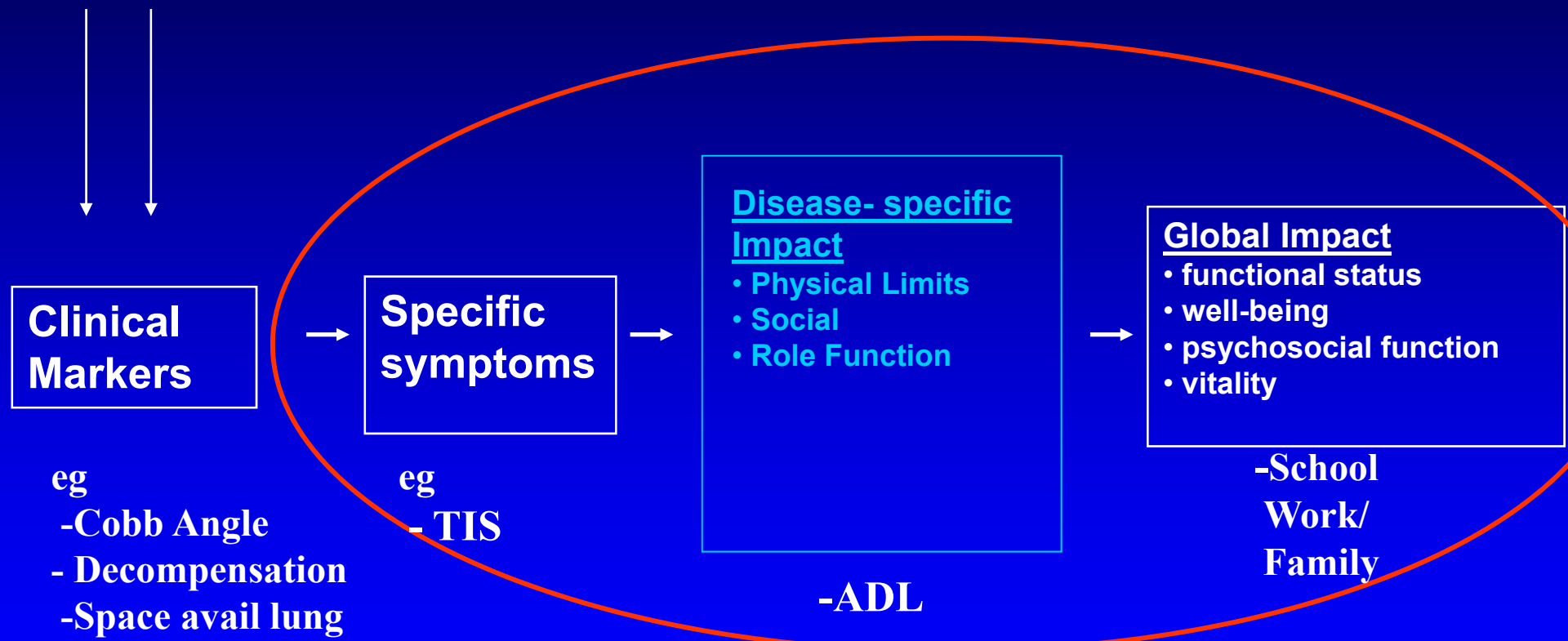
Health Related Quality of Life (HRQL)



Physical Function

- ROM
- **Alignment**
- Mobility
- ADL
- Sports

Disease-Specific and Generic Measures Are Complementary and Both Necessary



Health-Related QOL

Intrinsic Difficulties in Pediatric Quality of Life Assessment

- **Developmental** issues -> need for age-based norms
- Often need to use **parent** as proxy- **VALID** ?
- Many procedures in pediatrics are “**prophylactic**”
 - i.e. intended to prevent future disability...scoliosis
- Long periods of **follow up** needed
- **Natural history** of disease unclear

Psychometrics

“the science of measurement”

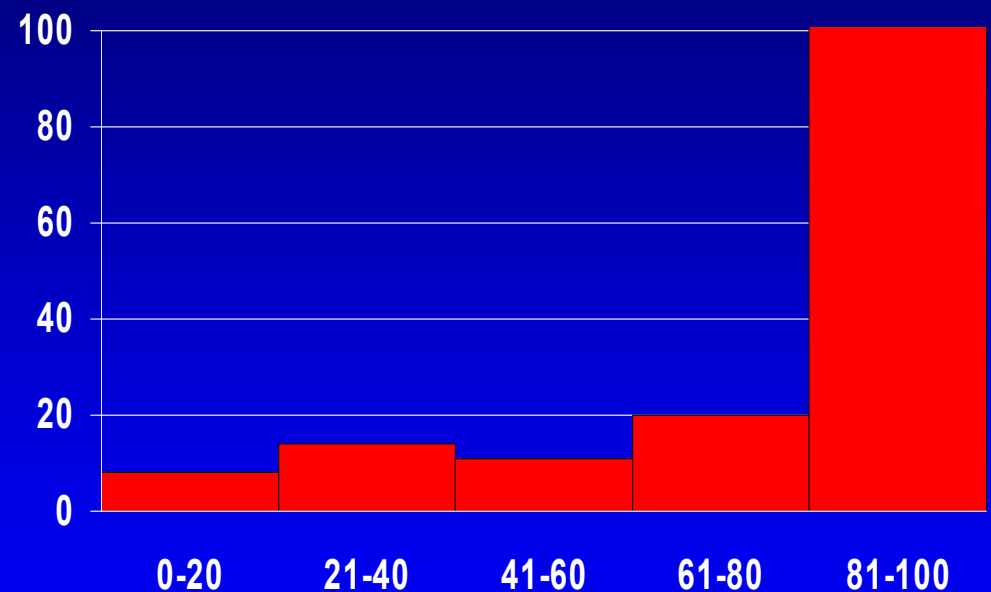
- Score Distribution
- Validity (criterion, concurrent, face, discriminant)
- Reliability / Reproducibility
- Responsiveness

Score Distribution

- Ceiling Effects
 - All patients score near top of scale
- Floor Effects
 - All patients score near bottom of scale

SF-36 : Ceiling Effects in AIS

- “Fatal” ceiling effects
 - i.e. too many patients scored at high end of scale despite evidence for clinical differences between patients



Who are your patients ?



Validity

Does it measure what it is intended to measure?

- Concurrent / Criterion Validity
 - What is correlation with “ Gold Standard ? ”
- Discriminant Validity
 - Does the instrument discriminate among patients with different degrees of severity ?

Reliability

Is it free from random error ?

- Internal consistency – do items on the same scale vary with each other ?
 - Cronbachs alpha
- Reproducibility- test/retest comparison
 - Intraclass Correlation Coefficient

Responsiveness

Is it sensitive to change over time / treatment ?

- Does the instrument reflect changes in disease status ?
- Pre Vs Post Op

QOL is affected in Adult Patients with Scoliosis

- **Schwab et al; Spine 03** Adult scoliosis patients have lower SF-36 scores
- **Albert et al; Spine '95** - SF-36 scores improved in adults after scoliosis surgery
- **Danielsson et al, Spine '01**- Lower physical function, not mental health scores regardless of treatment or curve size

QOL in AIS: Vitale et al, JPO 2003

QOL Before and After Scoliosis Surgery

- 40 patients followed longitudinally
- Min follow-up: 12 months
- Average # of spinal levels fused: 10
- Average degree of curvature:
 - Preop: 54 degrees
 - Postop: 22 degrees
- CHQ , PODCI, SRS Measure

Newer Pediatric Measures : CHQ

- Child Health Questionnaire (CHQ)
 - Landgraf and Ware '90. Released 1/97
 - Versions: PF 98/ PF 50/ PF 28/ CF 87
 - age-adjusted normative values available
 - extensively validated

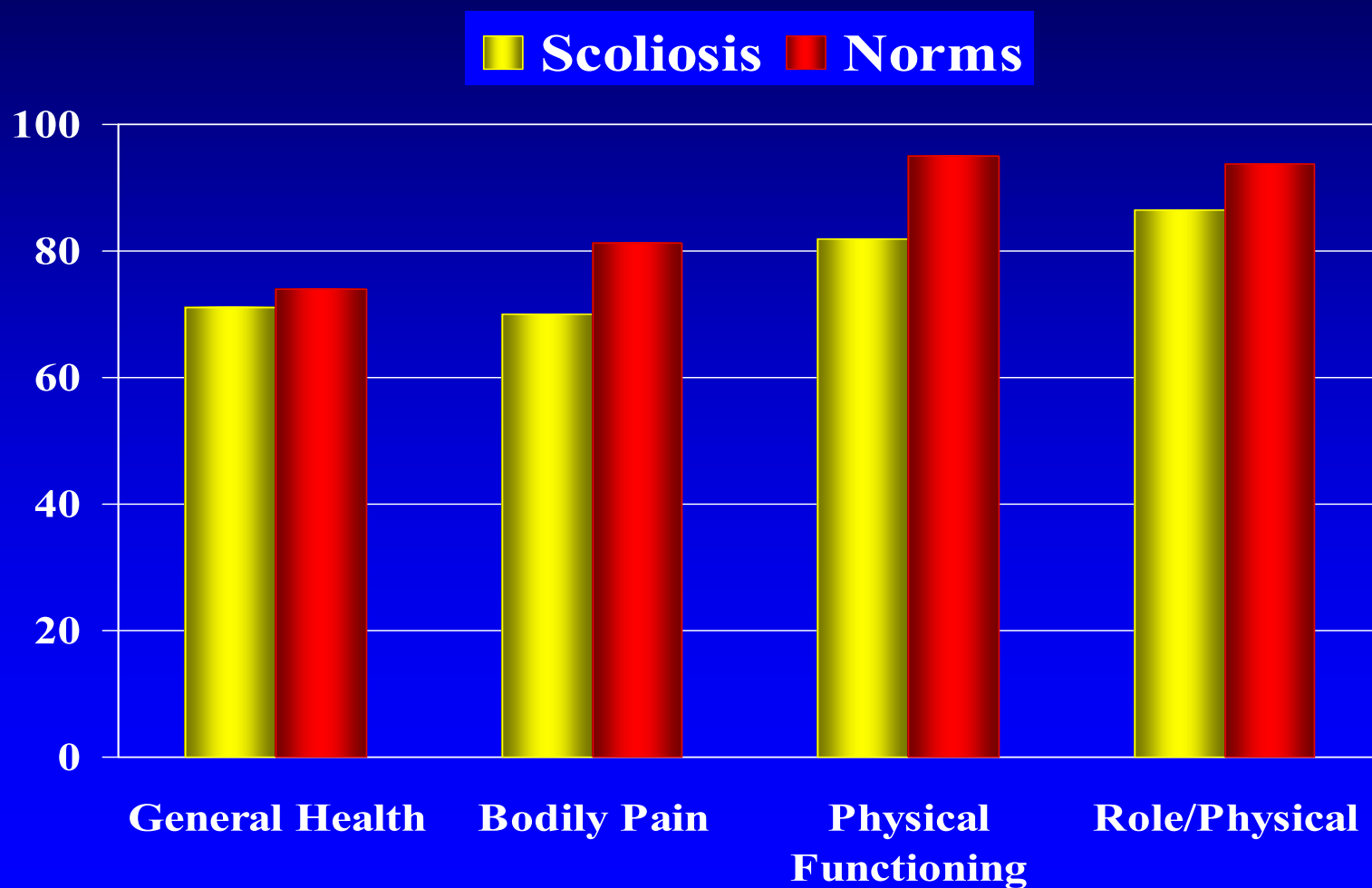
Newer Pediatric Measures: PODCI

- AAOS PODCI: *Pediatric Outcomes Data Collection Instrument*
 - “population specific” for pediatric orthopaedics
 - Separate child and parent forms – 108 q
 - Norms available

Newer Pediatric Measures: SRS

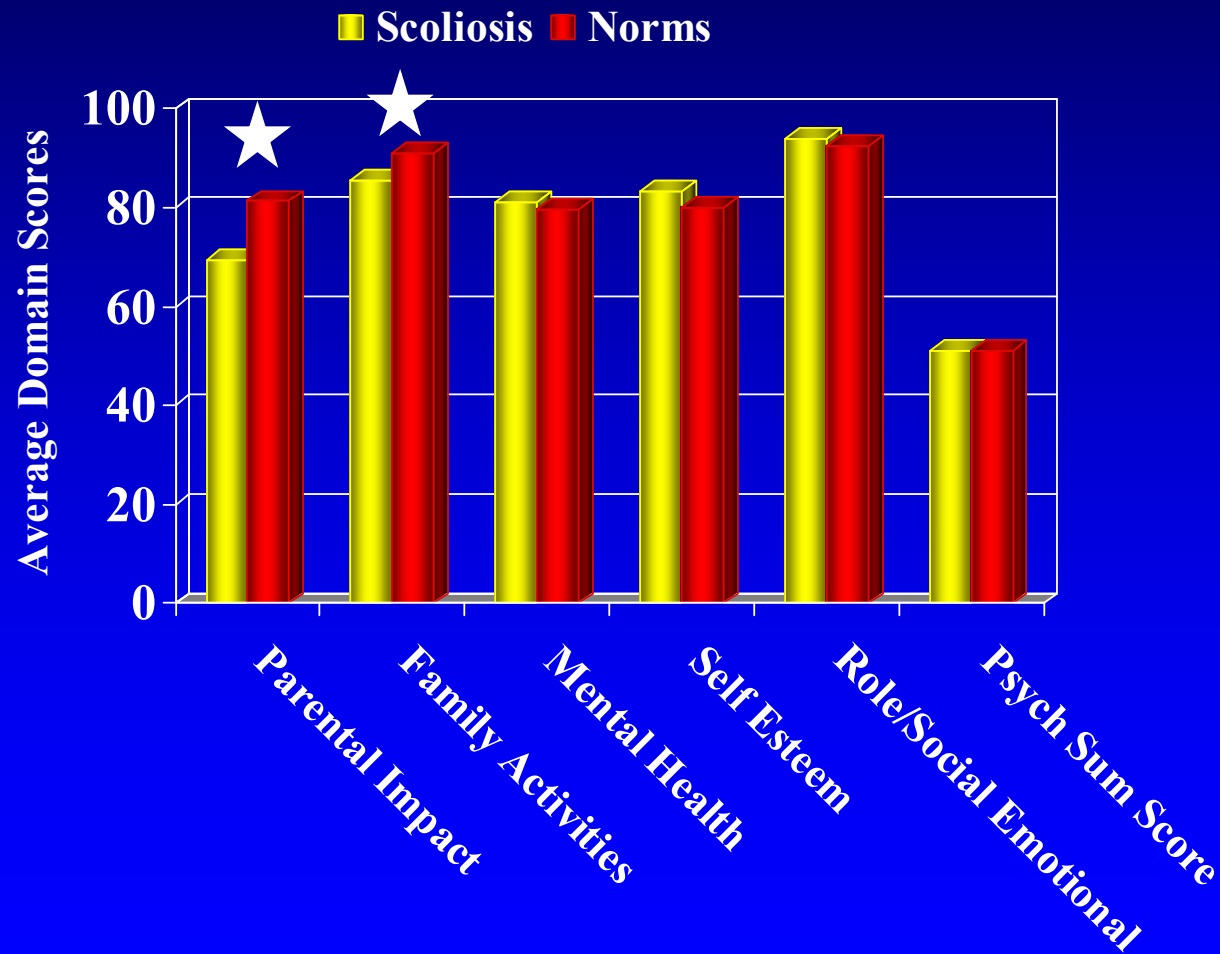
- **Haher et al, Spine 1995**
 - Meta-analysis of Surgical Outcomes in AIS: 2926 patients
 - Need for standardized measure of *patient* outcome
- **Haher et al, Spine August 1999**
 - **Scoliosis Research Society Instrument (SRS)**
 - 24 items; 7 domains
 - Good initial validity and responsiveness

CHQ : Children with Scoliosis Have Lower Physical Scores than Norms

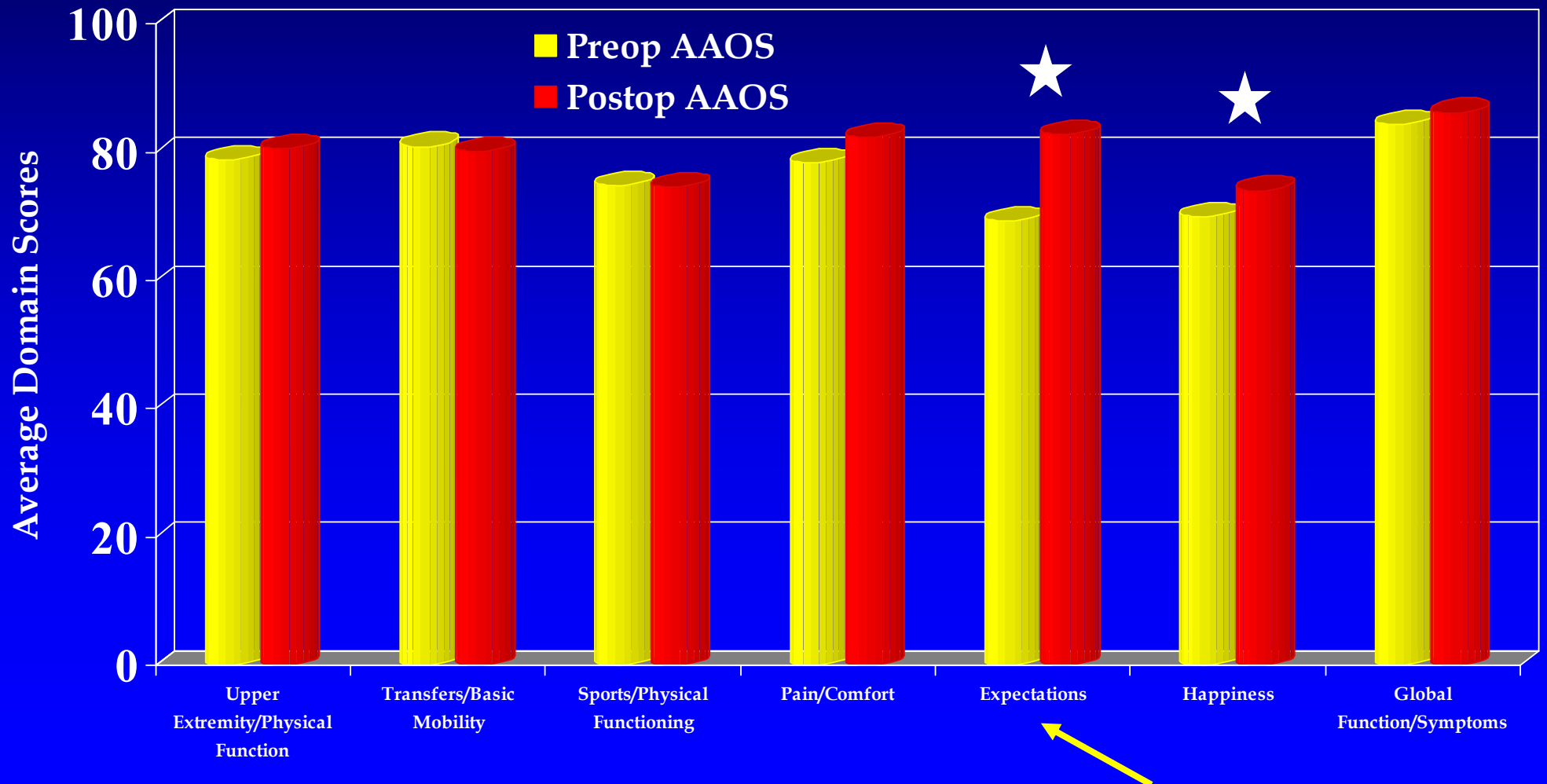


Psychosocial Scores

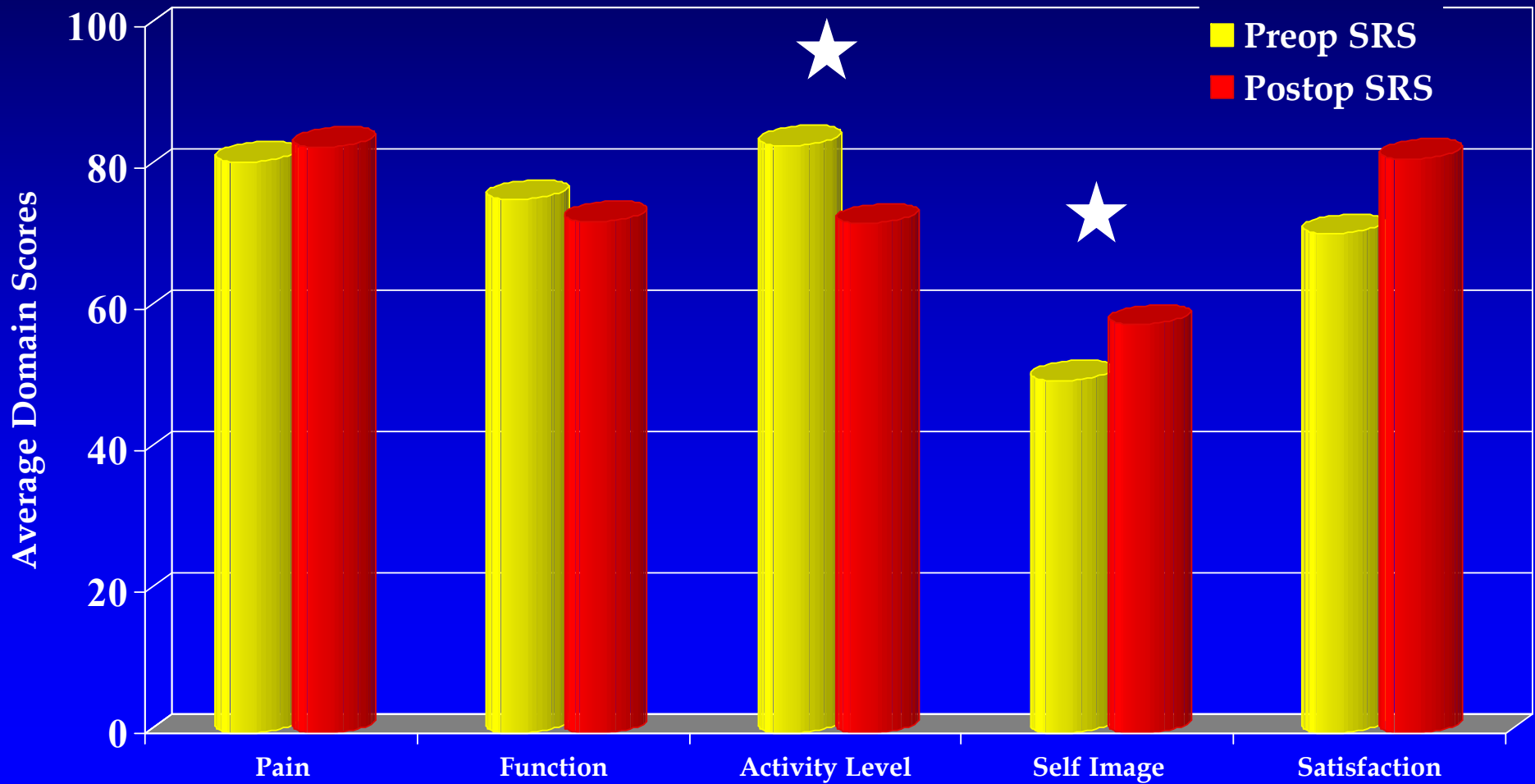
Some Differences in “Family Health”



PODCI: Before and After Surgery



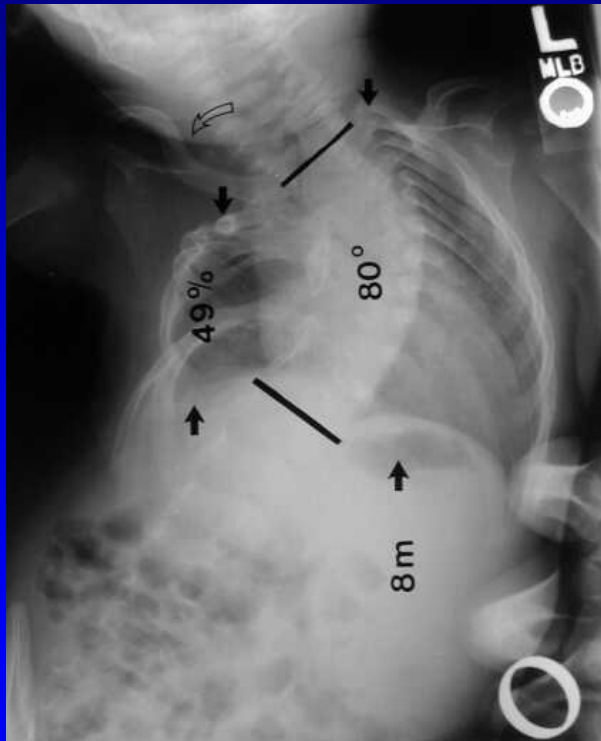
SRS: Before and After Surgery



HRQOL in AIS

- Appropriate measures pick up **some** differences in self-reported health status
 - Pain, physical health, self image, family fx
- Expectations met (PODCI) and satisfaction high (SRS)
- Curve size does NOT seem to correlate with QOL

What are the quality of life issues in early onset scoliosis ?



- What is QOL in patients at baseline
 - ?effect of curve size, onset, comorbidities
- What is effect of treatment
 - Early fusion
 - Repetitive Surgery

Comorbidities and EOS

- Children with early onset scoliosis often have significant comorbidities and can rapidly develop thoracic insufficiency and pulmonary compromise.
- The effect of thoracic insufficiency, early onset scoliosis and associated problems can significantly effect the quality of life of these children

Early Spine Fusion is Associated with Adverse Pulmonary Outcome

- Respiratory function and cosmesis at maturity in infantile-onset scoliosis. Spine. 2003; 28: 2397-406.
 - Goldberg CJ, et al.
- Earlier and More Extensive Thoracic Fusion is Associated with Diminished Pulmonary Function: Outcomes after Spinal Fusion of 4 or more Thoracic Spinal Segments Before Age 5. Poster presentation, IMAST, Bermuda, 2004.
 - Emans JB, et al.
- The effect of early thoracic fusion on pulmonary function in non-neuromuscular scoliosis, SRS , Miami, 2005
 - Karol, L. et al.
- PFT and QOL after Early Fusion; POSNA, Ft Lauderdale, 2007
 - Vitale et al

Retrospective Cohort Study of Pulmonary Function, Radiographic Measures and Quality of Life in Children with Congenital Scoliosis:
An Evaluation of Patient Outcomes after **Early Fusion**

Vitale et al, 2006

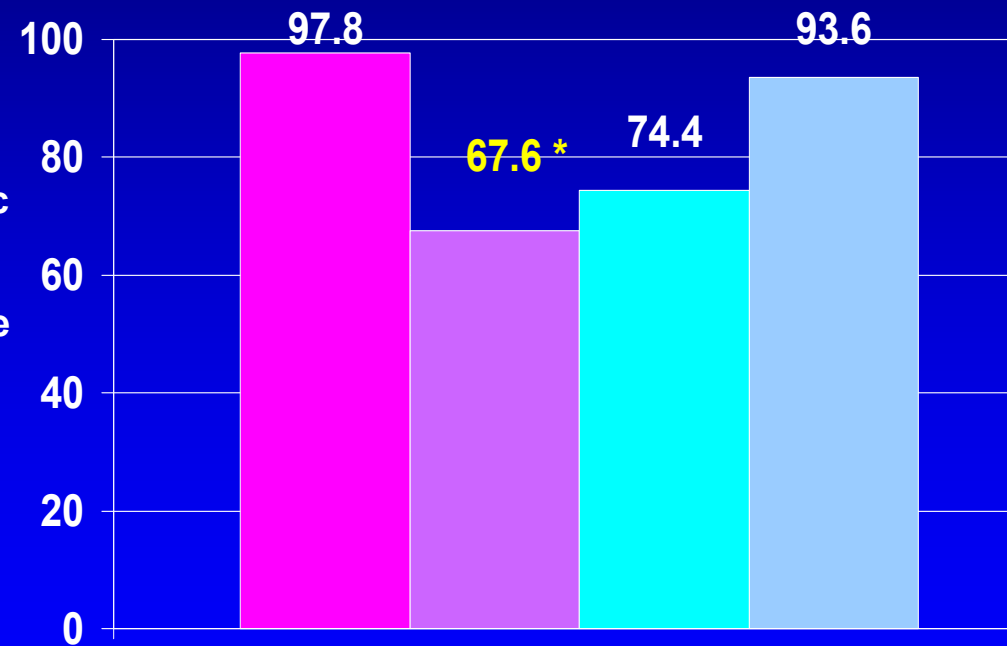
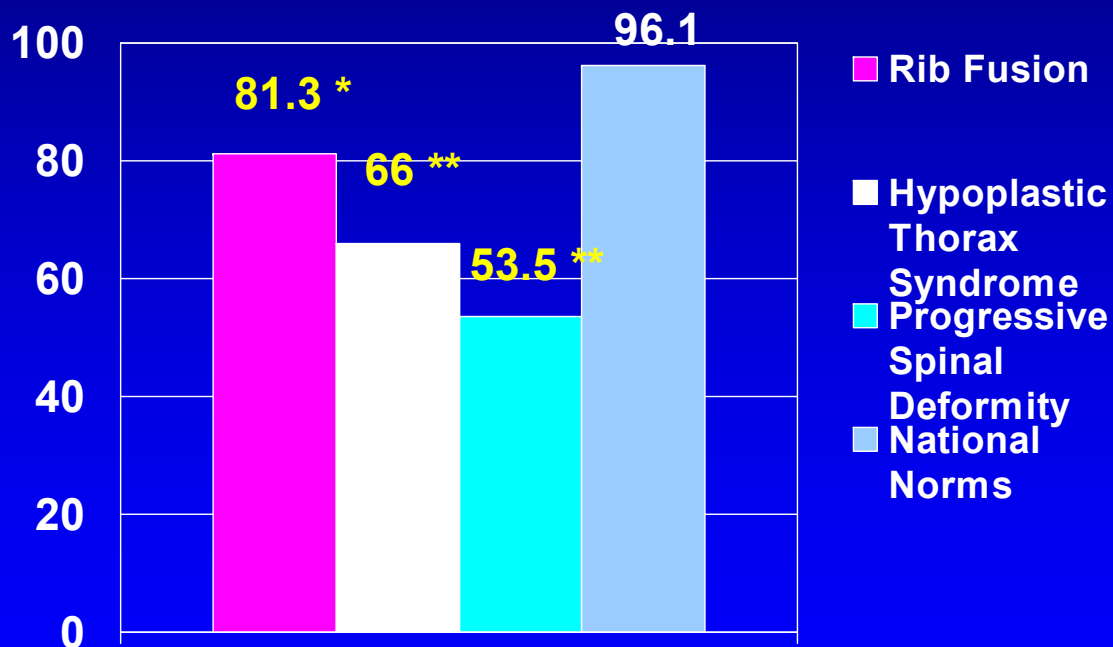
- 7 year follow up on 27 patients with early fusion (6 yrs avg) for congenital scoliosis
- Poor PFT, Poor QOL
- *Age at fusion and residual curve at follow up* seems to strongly drive lung function
- Quality of life appears to be largely independent of Cobb, age and other factors

Health Related Quality of Life in Children with Thoracic Insufficiency Syndrome

- Retrospective database review of original multi-center evaluation of the VEPTR
 - Child Health Questionnaire Parent Form (CHQ)
 - Age > 5 years
- 3 diagnostic categories:
 - Rib Fusion (RF, N=15)
 - Hypoplastic Thorax Syndrome (HT, N=17)
 - Progressive Spinal Deformity (PS, N=13)

Physical Functioning

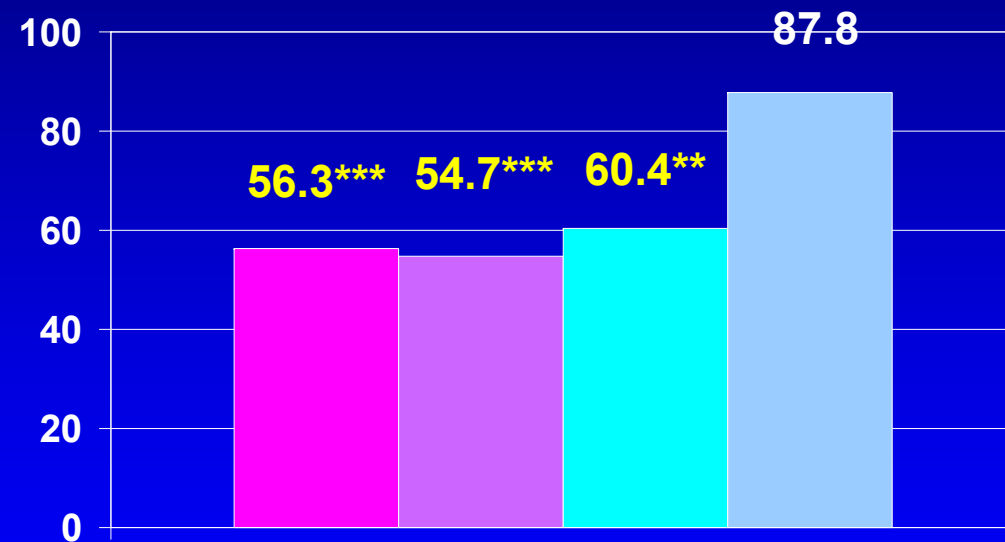
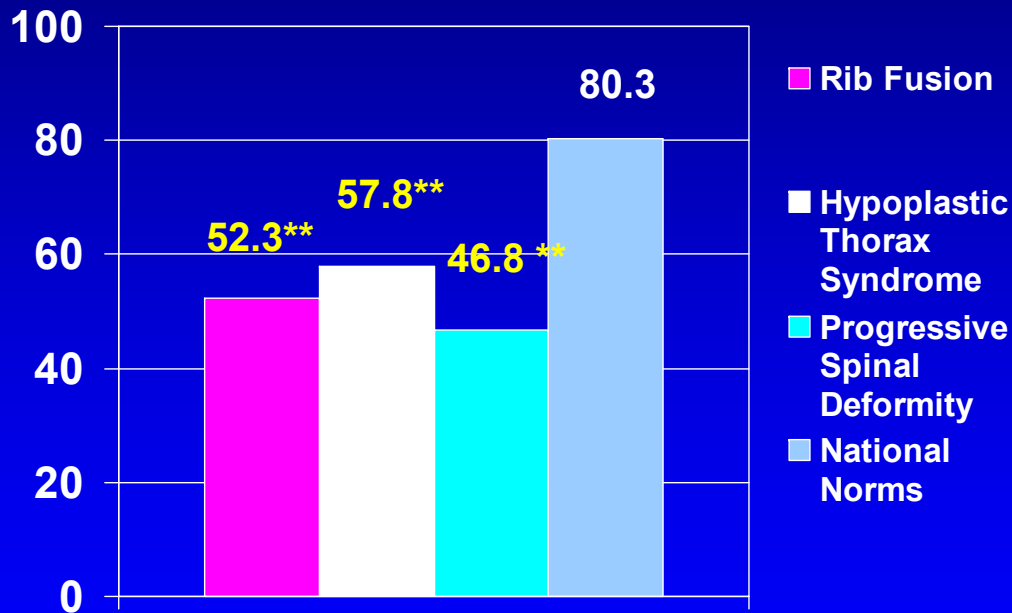
Role/Social Limitations - Physical



Large Differences in Physical Aspects of Quality of Life

Parental Impact - Emotional

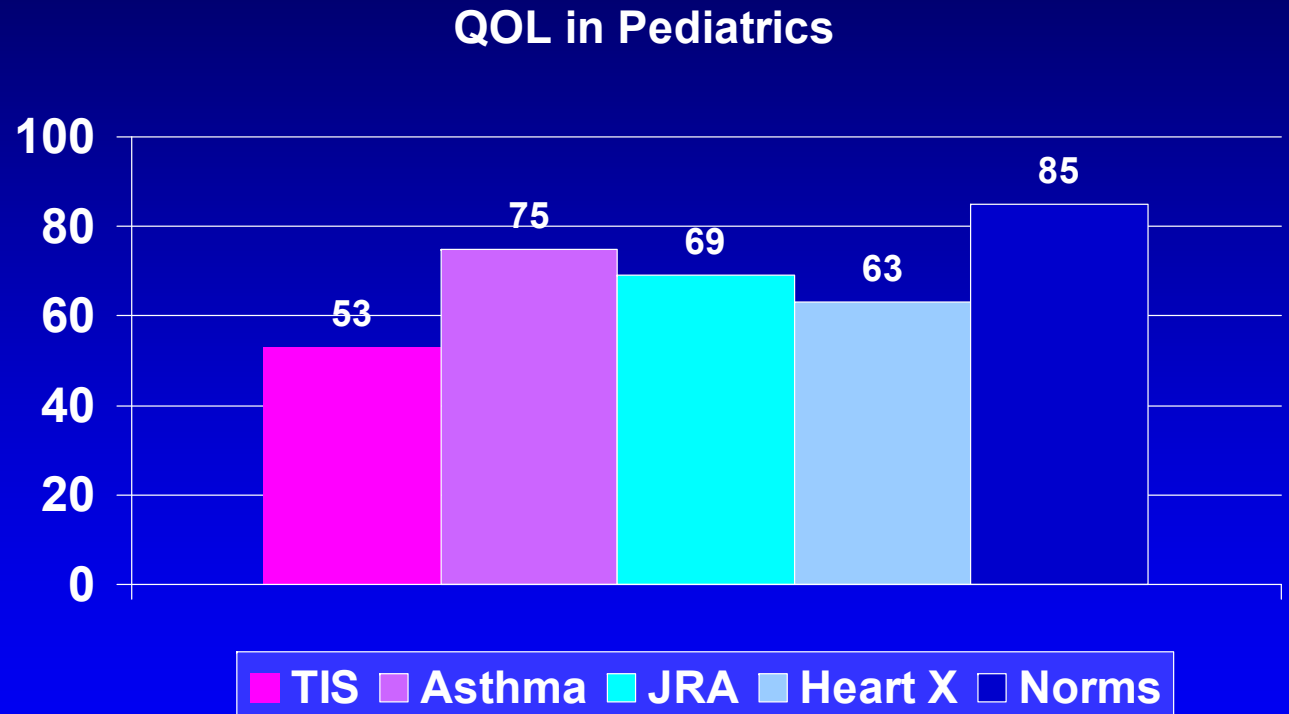
Parental Impact- Time



The Impact of Caring For a Child with TIS on the Family is Profound

Conclusions: QOL in TIS

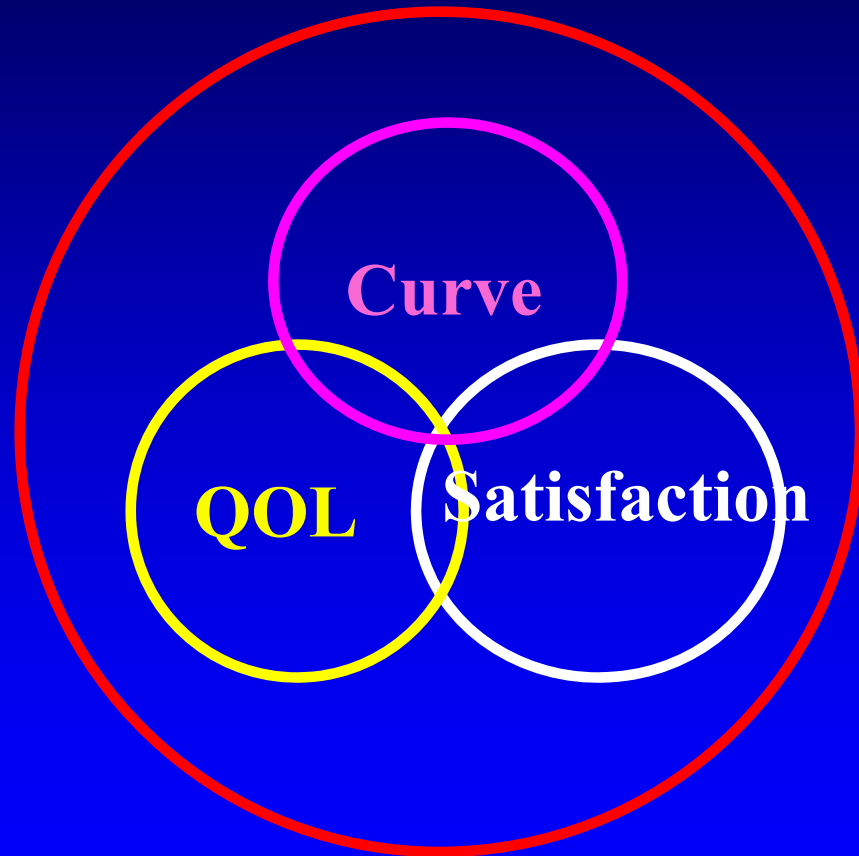
- These scores are among the **lowest observed in pediatrics**
 - Asthma
 - JRA
 - Heart transplant



Conclusions: QOL in TIS

- Patients with thoracic insufficiency syndrome have significant and profound perturbations in QOL when compared with other children
- Much different than AIS

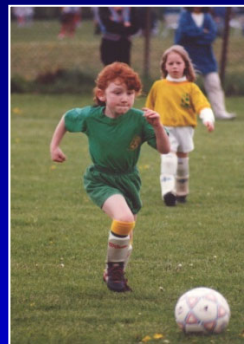
Traditional Endpoints and Patient Based Measures Dont Necessarily Correlate



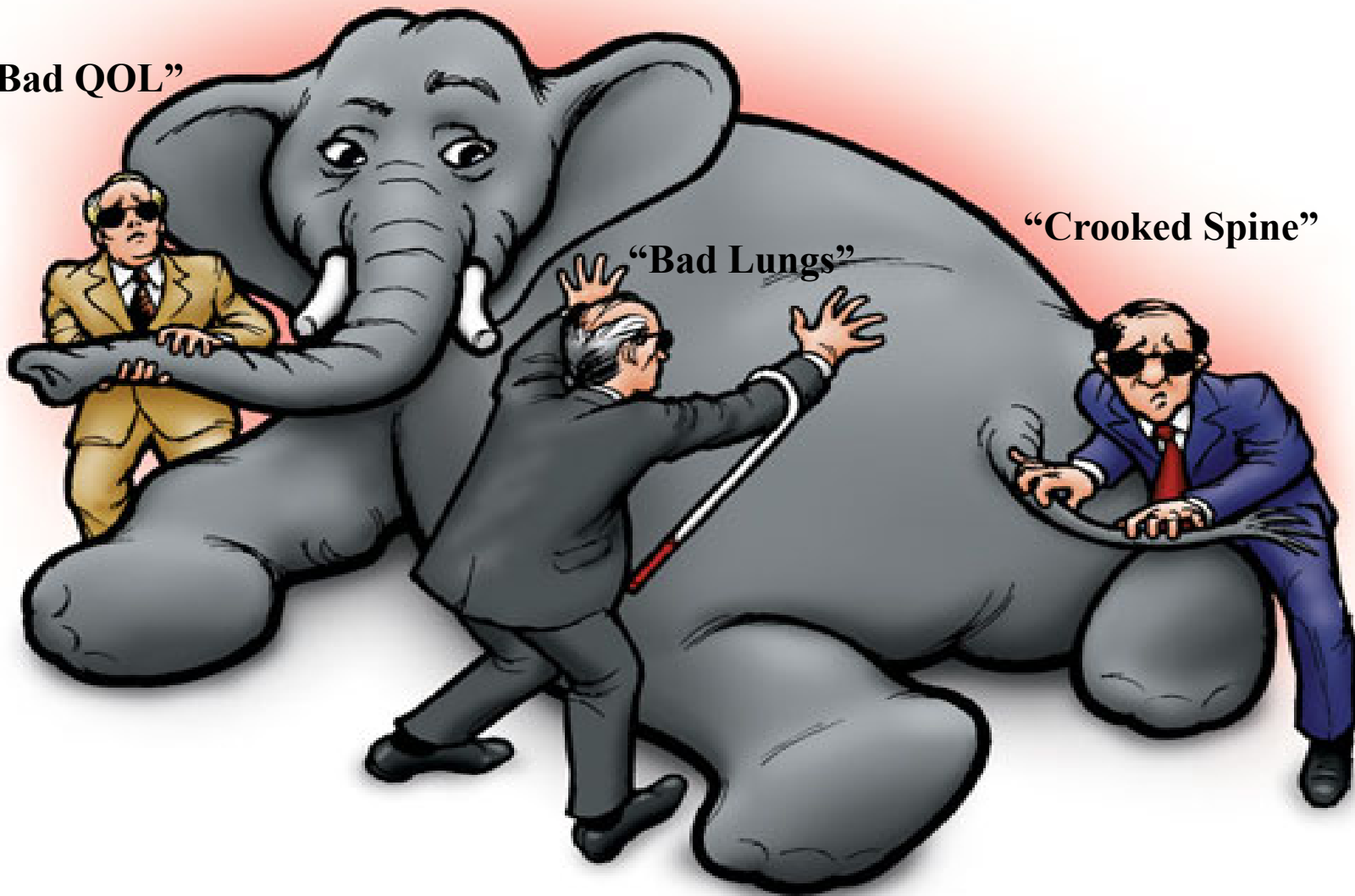
Separate Analyses are required

Towards a Disease Specific Measure

- We need a better ruler to examine HRQOL and responsiveness in EOS
- “What is the QOL effect of Repetitive Surgery”



“Bad QOL”

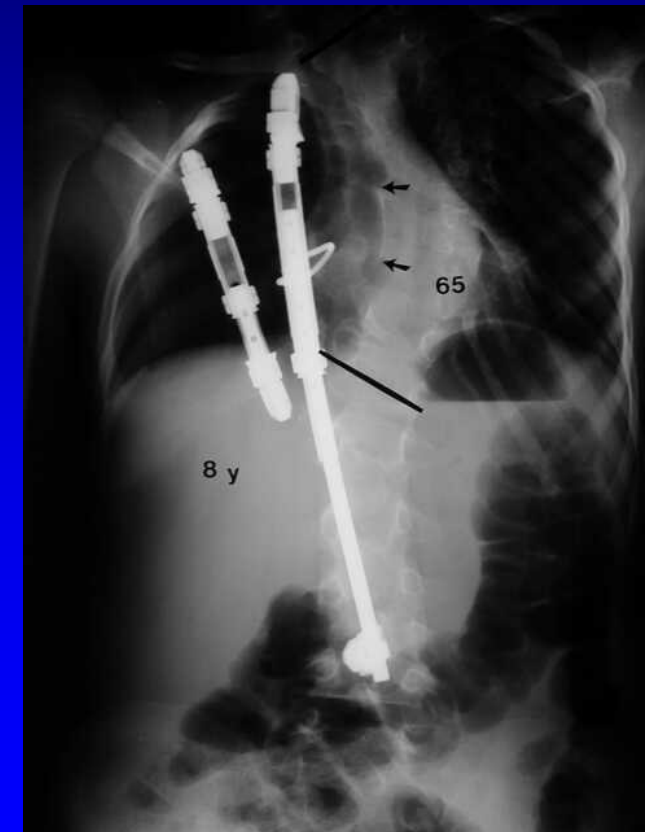
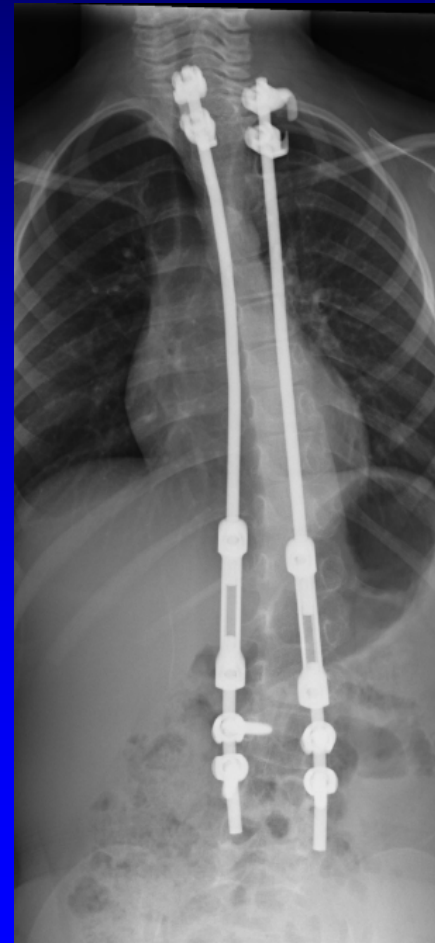


“Bad Lungs”

“Crooked Spine”

Conclusions

- EOS is bad disease
- QOL is ONE important outcome measure
- We need both disease specific measures and generic QOL measures



Thank You



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