Validation of the
Early-Onset Scoliosis Questionnaire (EOSQ): Responsiveness and Comparison with Normative Subjects

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Improving the Evidence Base in EOS

Development of a Research Infrastructure
Via four parallel efforts

Equipoise — Evaluating clinical equipoise in the field of EOS

Classification — Developing an EOS Subgroup Classification Schema to facilitate collaboration and communication

Endpoints — Development and Validation of a Disease Specific QoL Measure

Consensus Trial Structure — Determining inclusion criteria, treatment options and outcome measures for future research efforts

Why Do we Need an
Early Onset Scoliosis Questionnaire ?

- Realization that "technical", "traditional" endpoints have shortcomings

- *Different, but better* ?

Intrinsic Difficulties in Pediatric Quality of Life Assessment

- Many procedures in pediatrics are "prophylactic"
    - Disease is silent and endpoints are natural history

- Developmental issues -> need for age-based norms

- Often need to use parent as proxy- VALID ?

- Long periods of follow up needed

- Heterogenous populations

Multicenter VEPTR Study--CHQ

Vitale et al. J Pediatr Orthop 2008; 28:239-243

QOL in Pediatrics

Legend: ■ TIS ■ Asthma ■ JRA ■ Heart X □ Norms

Values shown: 53, 75, 69, 63, 85
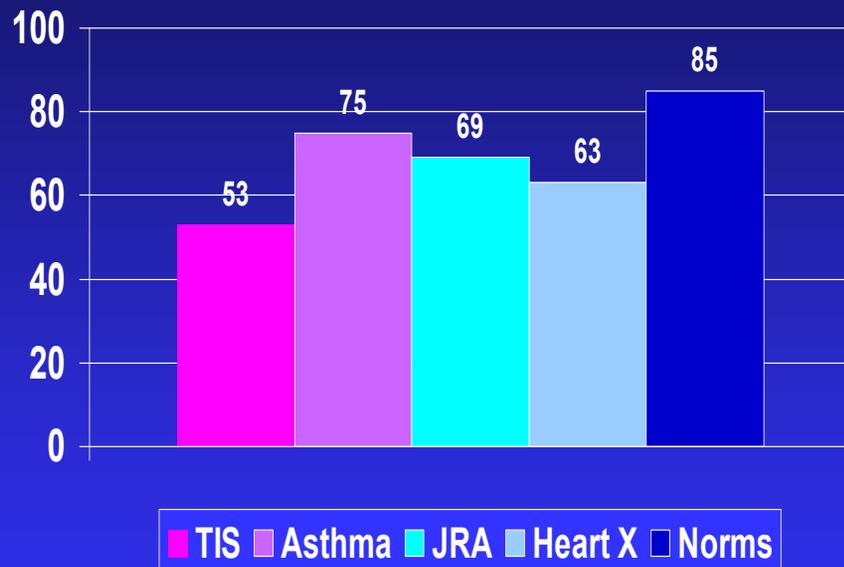
- **CHQ scores are lower than those with:**
  - **Asthma**
  - **Juvenile Rheumatoid Arthritis**
  - **Heart transplant**

- Concerns about responsiveness to clinical change after intervention
  - Instrument not sensitive?
  - Intervention not effective?

- CHQ did not adequately reflect issues unique to the EOS population

- CHQ not public domain

- CHQ only for use in children >5 y.o.

Development and Initial Validation of EOSQ

Literature Review

Existing Instruments

Expert Opinion

Semi-structured Interview Topic Items

Parent interviews

Master List of 75 Items

Content Validity
• Relativity and Clarity

Construct Validity
• Item Statistics

EOSQ

Initial Validation

Content Validity

- **10 parents, 14 physicians, and 3 health care providers, evaluated <u>relevance</u> and <u>clarity</u> of questions**

- **Content validity indices (CVIs) were calculated**

Item Statistics

- *Item Distribution*
  - Ceiling and Floor Effect (<80%)
    - Mean (3.0 for 5 point Likert scale)
      - Normal Distribution
- *Item Reliability*
  - Median Item Correlation (r= 0.4-0.5 between items within domains)
- *Item Validity*
  - Item Total-Item correlation (r=0.3-0.5 when a domain has more than three items. Correlation in 0.2 and .6)

Measuring Quality of Life in Children With Early Onset Scoliosis: Development and Initial Validation of the Early Onset Scoliosis Questionnaire

Jacqueline Corona, MD,*† Hiroko Matsumoto, MA,*†
David P. Roye, Jr, MD,*† and Michael G. Vitale, MD, MPH*†

J Pediatr Orthop. 2011 Mar

1. General Health (2 items)
2. Pain/Discomfort (2 items)
3. Pulmonary Function (2 items)
4. Transfer (1 item)
5. Physical Function (3 items)
6. Daily Living (2 items)
7. Fatigue/Energy Level (2 items)
8. Emotion (2 items)
9. Parental Burden (5 items)
10. Financial Burden (1 items)
11. Surgery (2 items)
12. Satisfaction (2 items)
13. Treatment Outcome (7 items

OFFICE USE ONLY		Study ID:		Date: / /

General Health

1. In general, you would say your child's health has been:

Poor	Fair	Good	Very good	Excellent

2. How often has your child missed school due to his/her health condition?

All of the time	Most of the time	Some of the time	A small amount of time	None of the time

Pain/Discomfort

3. How often has your child had pain/discomfort?

All of the time	Most of the time	Some of the time	A small amount of time	None of the time

4. How often did pain/discomfort interfere with your child's physical activities?

All of the time	Most of the time	Some of the time	A small amount of time	None of the time

5. How often did pain/discomfort interfere with your child's sleep?

All of the time	Most of the time	Some of the time	A small amount of time	None of the time

Pulmonary function

EOSQ: 13 Domains and 33 Items

Development and Validation of the EOSQ

- Phase 1: Development (N = 10) – **COMPLETE**

- Phase 2: Initial Validation (N = 28) – **COMPLETE**

- Phase 3: Prospective Multicenter Validation

    – Target Sample Size: N = 40

- Phase 4: Collection of age-based normative data

    – Target Sample Size: N = 20/ age group

Purpose

- **To examine responsiveness of the EOSQ to changes before and after treatments among EOS patients undergoing growing instrumentations.**

- **To establish age specific normative values to guide the interpretation of the EOSQ scores.**

Methods

Participating Sites

Site	PI	Pre-OP	1st	2nd
CHONY	Michael G. Vitale	26	20	15
Primary Children's - Utah	John T. Smith	11	6	1
Boston Children's	John Emans	9	8	5
UCSD	Behrooz Akbarnia	12	10	9
CHLA	David Skaggs	6	2	0
	TOTALS:	**64**	**46**	**30**

Methods

Procedures

Parents completed EOSQ at 3 time points:

- prior to initial instrumentation

- prior to first lengthening (or 4-6 mo post-Shilla)

- prior to second lengthening

Inclusion

- EOS (Diagnosed before age of 8)

- No prior surgical treatment

- Cobb angle greater than 20 degrees

- Planned to undergo surgical treatment
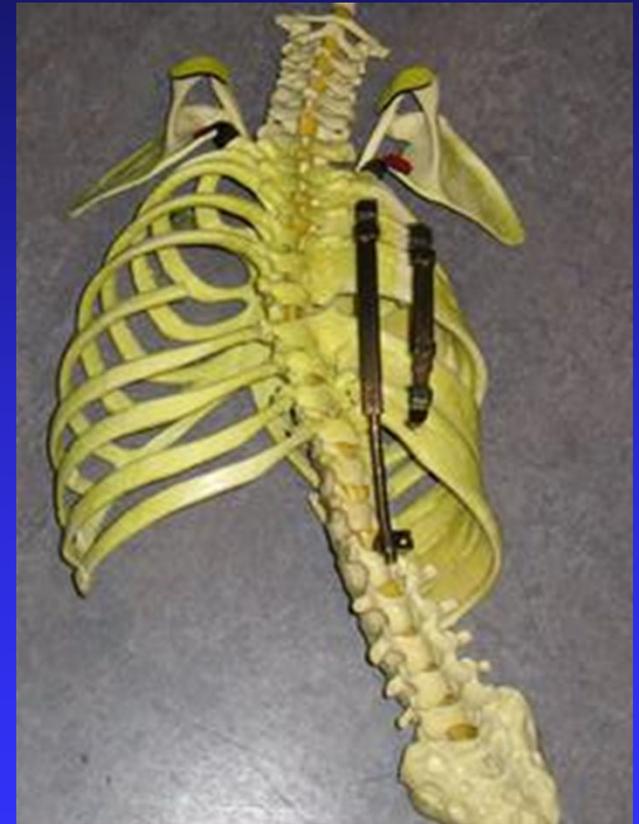
Participants (N = 64)

Mean age 6.0 at Index (preop);

VEPTR	N = 34	53.1%
Growing Rod	N = 26	40.6
Shilla	N = 4	6.3

Results: All Patients

All Pts	All		Growing		VEPTR	
	1st (n=46)	2nd (n=30)	1st (n=21)	2nd (n=14)	1st (n=24)	2nd (n=16)
General Health	↑			↓		
Pain				↑	↓	↓
Pulmonary						
Transfer						
Physical			↑			
Daily Living				↓	↓	
Fatigue						
Emotion						
Parental	↑		↑	↓	↑	↑
Financial					↓	
Total Score			↑			

Results: Neuromuscular Patients

NMD Pts	All		Growing		VEPTR	
	1st (n=16)	2nd (n=9)	1st (n=7)	2nd (n=2)	1st (n=9)	2nd (n=7)
General Health	↑					↑
Pain			↑			
Pulmonary	↑					
Tranfer						
Physical	↑		↑		↑	
Daily Living						
Fatigue	↑				↑	
Emotion	↑				↑	
Parental	↑	↑	↑		↑	↑
Financial			↑			
Total Score	↑		↑			

Patient MC

SMA Type 1

- 7 y/o boy
- GJ Tube
- TIS Atelectasis mult pneumonia
- Baseline continuous nasal BIPAP

78
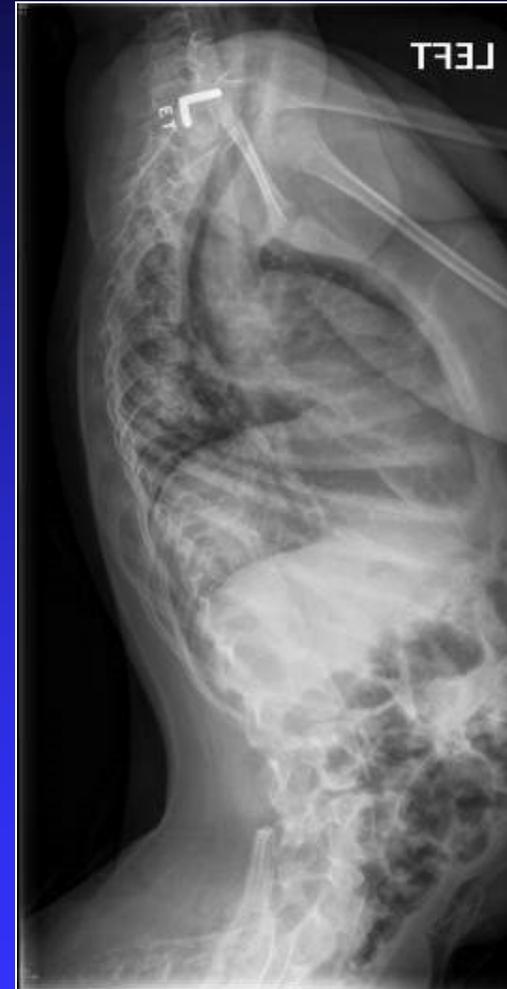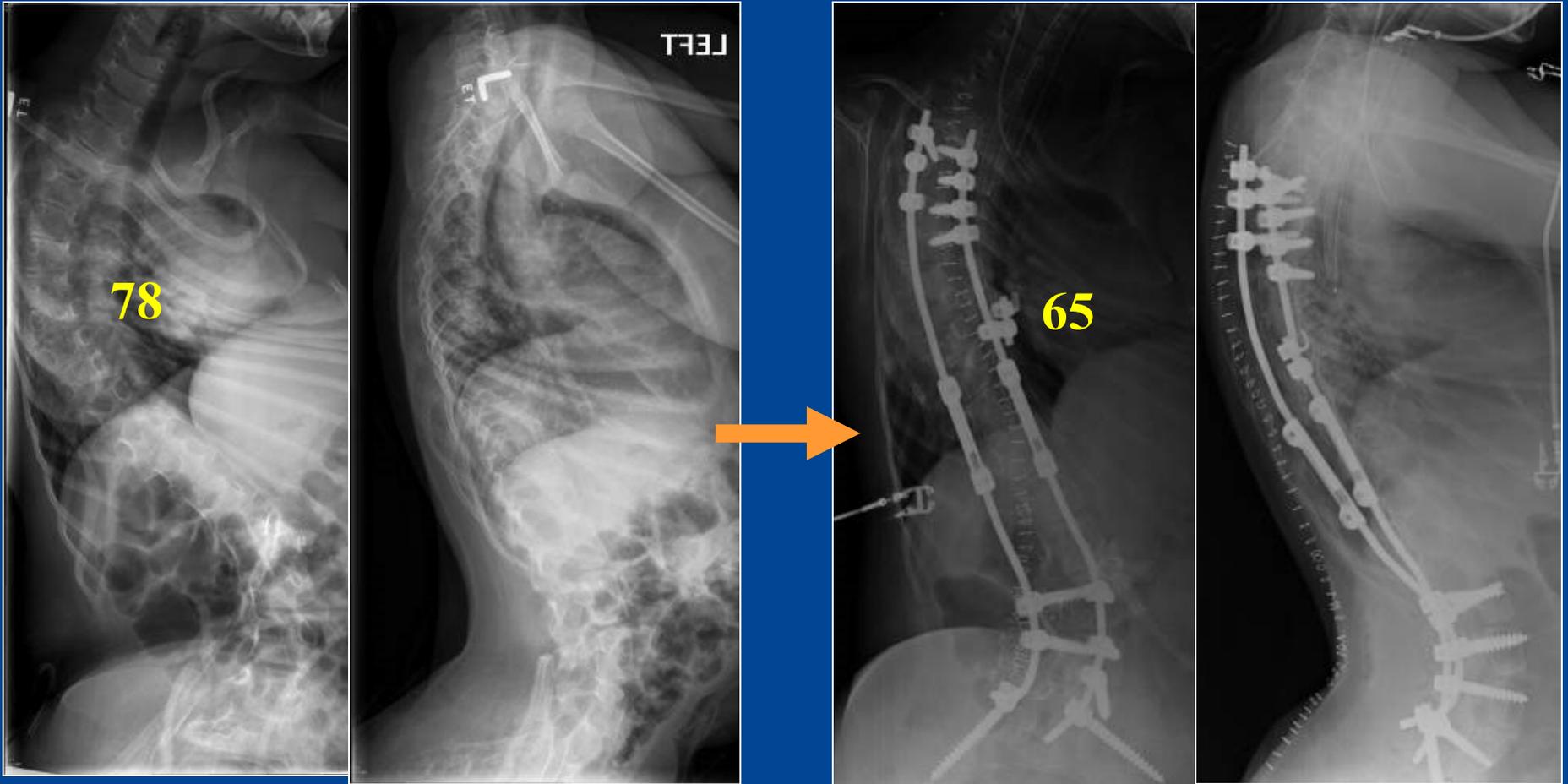
Patient MC

**Fusion T3 to T6 and L3 to Sacrum
with bilateral Growing Rods**

# Patient CP : Jarcho-Levin Syndrome
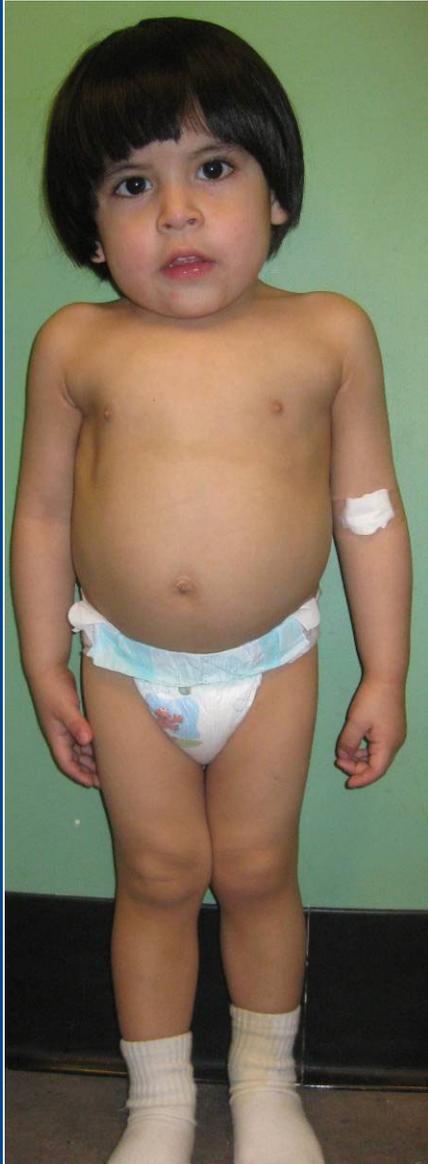
EOSQ: 16

Patient CP : S/P Contralateral VEPTR Placement

EOSQ: 16->24
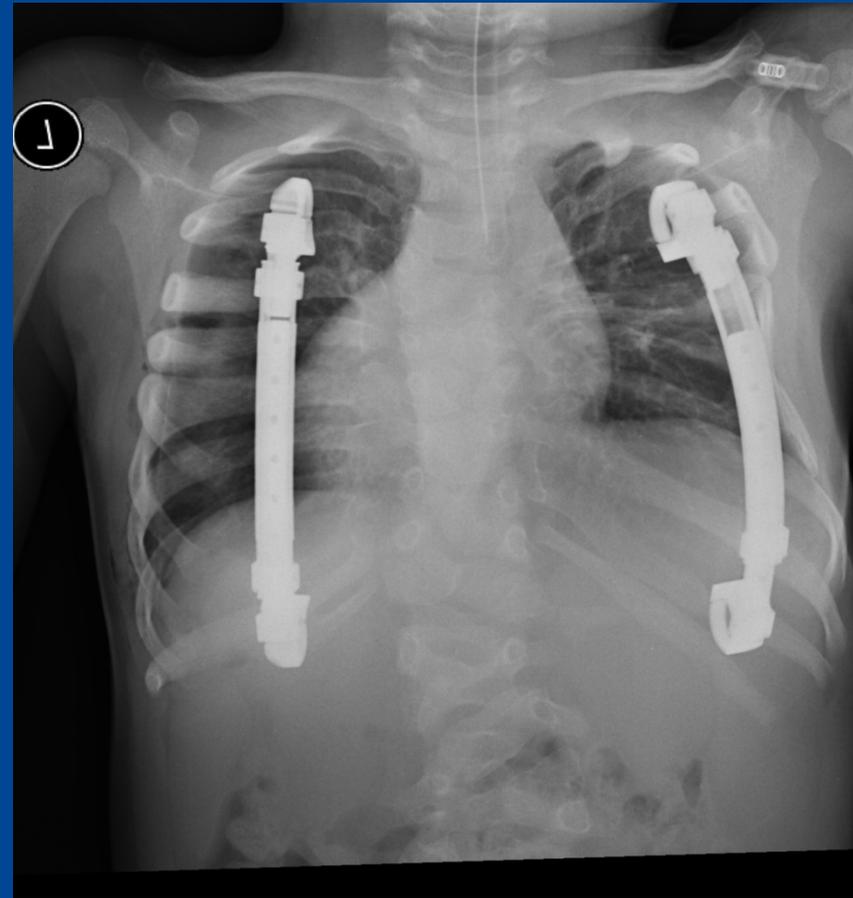
3/9/2011

Results

- **In NM patients, changes were noted in every EOSQ domain <u>except for the Transfer Domain</u>**

  - "How often has your child's health condition limited his/her access to public places?"

- **Effect sizes small to medium but significant**

Development and Validation of the EOSQ

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  – Target Sample Size: N = 40

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  – Target Sample Size: N = 20/ age group

Normative Data

- **128 patients in good health (ex. uncomplicated fracture follow-up) were recruited and their parents completed the EOSQ**

  – **Seems appropriate for age between 0-18.**

Normal Pts completing EOSQ		
Age	N =	EOSQ Score
0-1y	1	90
1-2y	8	99.1 +/- 9.6
2-3y	13	100.5 +/- 6.8
3-4y	14	105.9 +/- 4.4
4-5y	11	104.6 +/- 4.9
5-6y	12	104.8 +/- 8.1
6-7y	11	102.3 +/- 8.4
7-8y	7	106.8 +/- 3
8-9y	11	107.9 +/- 2.0
9-10y	5	108.2 +/- 1.6
10-18y	38	102.4 +/- 8.9

EOS Patients

	N	EOSQ Score
Pre-Op	64	76.8 +/- 18.7
1ST	46	77.6 +/- 16.6
2ND	30	75.9 +/- 18.3

Conclusion- "EOSQ 24"

- **EOSQ is valid, responsive measure**

- **Few ceiling/floor effects;**

- **Picks up change around surgery**

- **Easy to administer -24 items, 11 domains**

- **Scoring pending**

Early Onset Scoliosis Questionnaire (EOSQ 24)

FINALIZED!

- **Questionnaire with 24 items, 11 domains**

1. **General Health (2 items)**
2. **Pain/Discomfort (2 items)**
3. **Pulmonary Function (2 items)**
4. **Transfer (1 item)**
5. **Physical Function (3 items)**
6. **Daily Living (2 items)**
7. **Fatigue/Energy Level (2 items)**
8. **Emotion (2 items)**
9. **Parental Burden (5 items)**
10. **Financial Burden (1 items)**
11. **Satisfaction (2 items)**

Translation

- **Spanish Translation**

  – **Dr. David Farrington**

  Hospital Universitario Virgen del Rocío, Sevilla, Spain

- **Turkish Translation**

  – **Dr. Eda Tonga**

  Baskent University, Ankara/Turkey

Instrumento de Medición Específico para Escoliosis de desarrollo temprano

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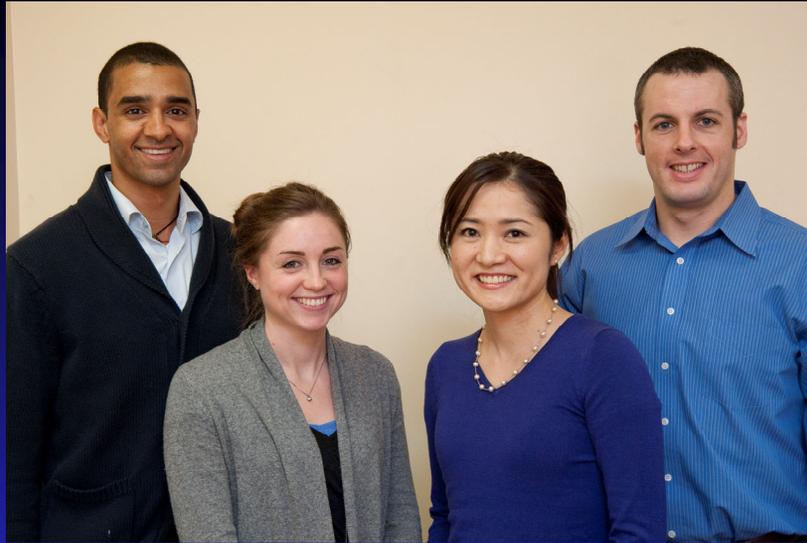
Thank You

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