Development of Deployable Predictive Models for MCID of 2 year Outcomes across All Commonly Used HRQOL Instruments in Adult Spinal Deformity Surgery: Results in 570 Patients from 17 Hospitals

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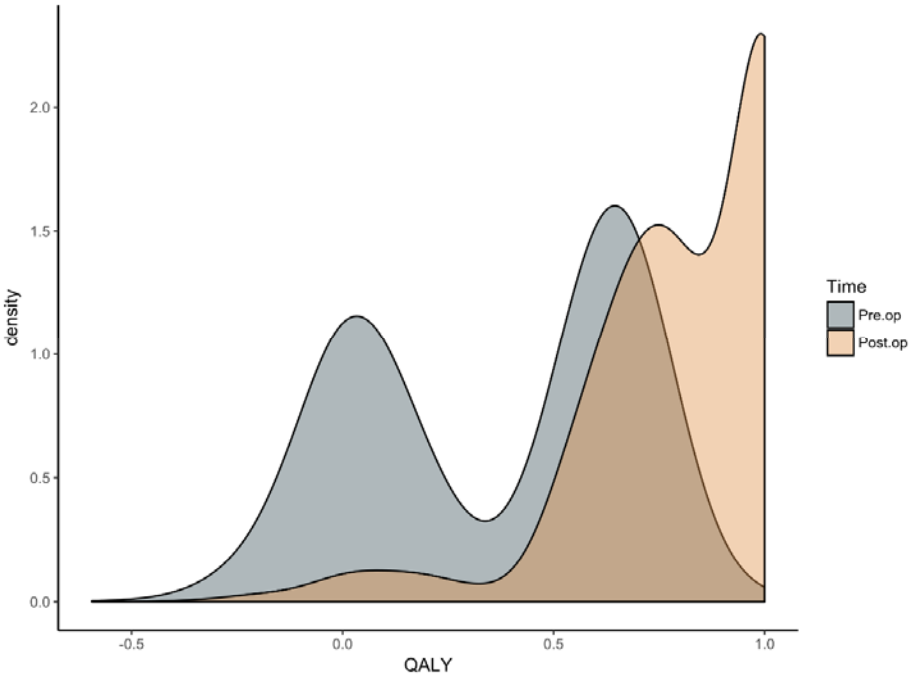
- ASD surgery is costly with variable outcomes; in some series only 50% of patients achieve MCID improvements.
- 1 & 2-year outcomes after ASD surgery present highly inherent variance
- Self-reported HRQOL are not perfect measures, but are the best up-to-date
- Shared-decision making: moving from *ambiguity to uncertainty*
- Predictive analytics may accurately model HRQOL improvements after ASD surgery.
- Predictive modeling may be useful in shared-decision making and surgical planning.

Self-reported HRQoL measures – EQ5D

- PROMS present inherent measurement error, 10%
- What matters most, sample size or data quality?
- Comparison with Hip replacement, Knee replacement and Groin hernia repair (Gutacker & Street 2017)



Hip Replacement – QALY distribution

Qual Life Res (2017) 26:2497–2505

Procedure	#groups	Development sample		Test sample		Reduced model	
		$adj\text{-}R^2$	RMSE	$adj\text{-}R^2$	RMSE	$adj\text{-}R^2$	RMSE
Hip replacement	55	14.3%	0.228	12.8%	0.218	1.5%	0.244
Knee replacement	59	19.4%	0.231	18.8%	0.224	2.1%	0.255
Groin hernia repair	60	27.0%	0.161	28.1%	0.158	1.3%	0.188

Development sample: April 2009 to March 2015. Test sample: April 2015 to March 2016. Reduced model only considers age, sex and symptom period for grouping and is estimated and tested on the development sample. R^2 is adjusted for number of predictor variables, i.e. groups

Replication, 28 controls, comorbidities and preop status

N=34,777, Training (N=26,084), Testing (N=8,693)

RMSE	Rsquared	MAE
0.2157674	0.1932373	0.1613225

30.2 – 82.5% precision in our models depending upon time frame & outcome

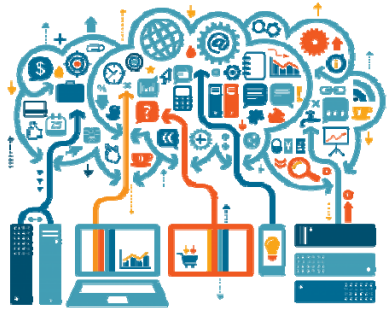
The objective of this study was to model HRQOL overall improvement, including the likelihood of achieving clinically important improvement, at 2 years postoperatively.

Methods

Retrospective analysis of two independent, prospective, multi-center ASD databases with identical fixed data fields

- European Spine Study Group (ESSG) Database
- International Spine Study Group (ISSG) Database

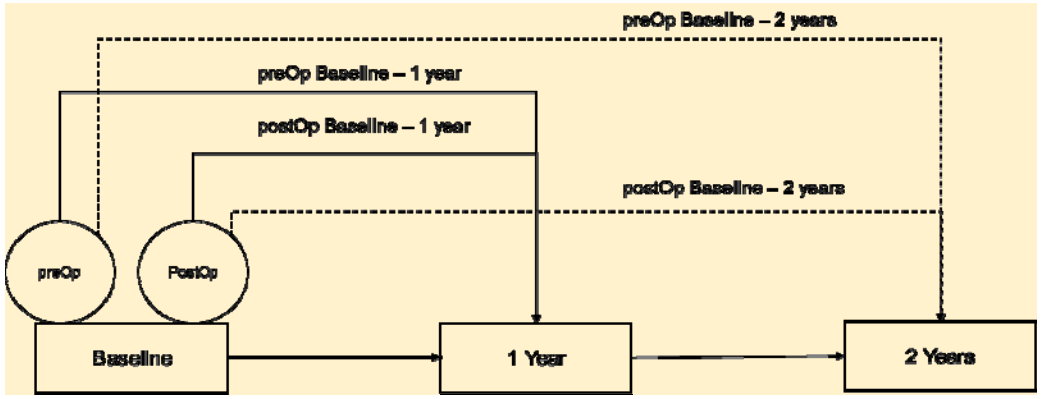
Predictive modeling (Machine Learning)



75 variables were used in the training of the models including:

a) patient characteristics
b) Surgical characteristics
c) Site-Fixed effects

8 different prediction algorithms were trained with 3-time horizons: baseline to 1yr-BL, 2yr-BL and 1yr-2yr:



- External validation was accomplished via an 80/20 data split for training and testing each model, respectively.
- 5-Fold cross validation within the training sample was performed.

Accuracy was measured as the mean average error (MAE; smaller is better) and R^2 values.

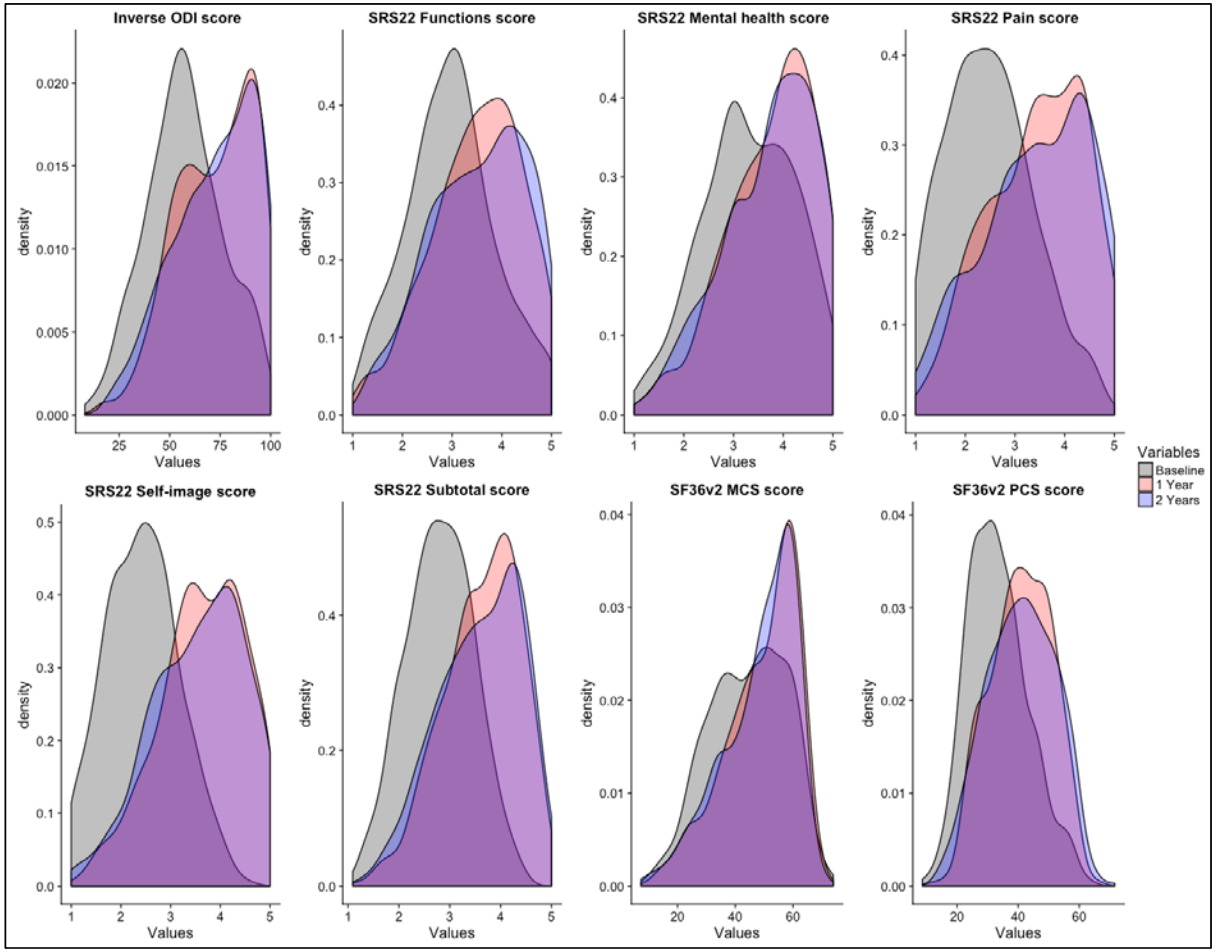
Inclusion criteria:

ASD ≥ 18 years
HRQoL scores (ODI, SRS22,SF36v2)
Surgically treated

1612 surgical patients:
24 hospitals
5 countries
57 surgeons
730.5 days mean FU

743 (46.1%) excluded since they were not yet eligible for 2-year follow-up due to on-going database enrollment

570 met inclusion criteria



Kernel distribution of Scores across the 8 outcomes at Baseline, 1 Year and 2 Years.
The shift to the right represents the population improvement.

Variable	Mean or %	SD	Min	Max
Pre-operative Baseline				
Gender (% women)	79			
Height (cm)	162.55	9.61	104.5	195.6
Weight (kg)	70.31	16.03	40	158.8
Age (years)	56.75	16.32	18.05	86.42
Sagittal alignment (SVA, cm)	55.64	69.55	-83.73	314.09
Coronal alignment (GCA, cm)	31.24	31.4	0	288.95
Major curve Cobb angle (°)	40.27	21	0	123.7
Pelvic tilt (°)	23.28	11.03	-12.66	67.9
1-Year Post-operative				
Sagittal alignment (SVA, cm)	23.83	51.38	-114.08	181.03
Coronal alignment (GCA, cm)	4.98	30.23	-162.17	113.25
Major curve Cobb angle (°)	9.09	23.43	-77.5	100.2
Pelvic tilt (°)	20.83	9.6	-15.29	61.13
2-Years Post-operative				
Sagittal alignment (SVA, mm)	30.36	54.23	-109.2	237.1
Coronal alignment (GCA, mm)	23.37	19.57	0	114.8
Major curve Cobb angle (°)	20.59	16.35	0	94.5
Pelvic tilt (°)	20.87	10.11	-6.3	61.87

Variable	Mean or %	SD	Min	Max
Previous spine surgery (%)	41.6			
Any major complication (%)	36.2			
Total surgical time (min)	345.74	134.47	43	802
Estimated blood loss (cc)	1660.16	1465.51	20	12200
Number of fused vertebral levels	10.7	4.21	0	23
Use of pelvic fixation (%)	59.5			
Use of interbody fusion (%)	54.4			
Use of Smith-Petersen osteotomy (%)	50.0			
Use of 3-column osteotomy (%)	20.8			
Length of hospitalization (days)	8.88	6.49	0	83

Variable	Mean or %	SD	Min	Max
Pre-operative Baseline				
Inverse ODI score[2]	57.55	18.89	8	100
SRS-22r function score	2.98	0.88	1	5
SRS-22r mental health score	3.31	0.93	1	5
SRS-22r pain score	2.49	0.88	1	5
SRS-22r self-image score	2.43	0.73	1	4.6
SRS-22r subtotal score	2.8	0.66	1.09	4.5
SF36v2 MCS score	44.53	13.19	10.59	73.53
SF36v2 PCS score	33.38	9.85	8.65	63.58
1-Year Post-operative				
Inverse ODI score[2]	72.44	18.94	16	100
SRS-22r function score	3.5	0.9	1	5
SRS-22r mental health score	3.75	0.88	1	5
SRS-22r pain score	3.45	0.96	1	5
SRS-22r self-image score	3.64	0.86	1	5
SRS-22r subtotal score	3.63	0.74	1.14	5
SF36v2 MCS score	49.34	12.32	10.48	73.95
SF36v2 PCS score	40.98	10.03	11.47	66.45
2-Years Post-operative				
Inverse ODI score[2]	72.51	19.98	17.78	100
SRS-22r function score	3.53	0.95	1.2	5
SRS-22r mental health score	3.72	0.92	1	5
SRS-22r pain score	3.44	1.06	1	5
SRS-22r self-image score	3.57	0.91	1	5
SRS-22r subtotal score	3.6	0.81	1.23	5
SF36v2 MCS score	48.57	12.43	7.32	70.87
SF36v2 PCS score	40.95	11.06	13.01	71.61

- Baseline HRQL scores are the main predictors of the outcomes after surgery (65%), the present is the best predictor of the future.

- Across all analyses there are some salient features:
  - baseline physical status is a determinant of future HRQL; patients with worse initial state present significant greater relative improvements than patients with better initial status.
  - Prior spine surgery is also a big predictor of both HRQL improvement and major complications incidence.
  - The additional relative predictive gain of surgical factors is limited; i.e. the number of SPOs compared to baseline status only presents an adjusted 2% relative importance.
  - Arthritis, hypertension and depression are comorbidities that have a greater effect on HRQL at 2 years.

Names	Importance
SRS22 subtotal score Baseline	**12.57%**
ODI score Baseline	**10.32%**
SF36v2 MCS score Baseline	**9.26%**
SRS22 MH score Baseline	**8.31%**
SF36v2 PCS score Baseline	**7.74%**
SRS22 function score Baseline	**7.33%**
SRS22 pain score Baseline	**5.73%**
Age Baseline	4.44%
SRS22 SI score Baseline	**3.82%**
Level of physical labor Null	3.23%
Prior Spine Surgery Yes	3.11%
Pelvic Tilt Baseline	2.45%
Hypertension Baseline	2.35%
Arthritis Baseline Yes	2.31%
Fused vertebrae	2.26%
Height cm Baseline	2.26%
Sagittal Balance Baseline	2.25%
Number of levels between UIV and LIV	2.22%
Major Curve Cobb Angle Baseline	2.12%
Depression Baseline Yes	2.00%
Weight kgs Baseline	1.97%
SPOs	1.95%

Aggregated Relative Variable Importance

*It is important to not interpret this variables as having a causal effect, due to the retrospective nature of the data

Models with the lowest MAE for each of the 5-time points were selected; ultimately the model had 82.4% predictive power. Patients with lower enrollment HRQOL were likely to appreciate the greatest improvements in HRQOL at 2-yr followup. Addition of surgeon and site to preoperative data increased the predictive power 1.8%. Site and surgeon fixed-effects played a crucial role in explaining outcome variance.

	HRQL instrument	Baseline Score	Baseline Probabilities	Depression and Hypertension	10% improve in physical HRQL scores	Waiting 5 years with a reduction of 10 % HRQL	Waiting 10 years with a reduction of 20 % HRQL	Post-op SVA 0mm	Post-op SVA 50mm	Post-op SVA 100mm	Number of Levels from 10 to 15	Range of variation across options
(1) Overall improvement	ODI	68	54.4%	55.1%	43.5%	67.6%	72.6%	54.4%	54.4%	54.4%	54.4%	29.1%
(2) Improvement over MCID	ODI	68	38.4%	39.1%	28.4%	52.0%	57.7%	38.4%	38.4%	38.4%	38.4%	29.3%
(1) Overall improvement	SRS22 function	3.2	65.0%	66.1%	51.4%	76.4%	83.5%	65.0%	65.0%	65.0%	65.0%	32.1%
(2) Improvement over MCID	SRS function	3.2	35.4%	36.5%	23.4%	48.3%	58.4%	35.4%	35.4%	35.4%	35.4%	35.0%
(1) Overall improvement	SRS22 MH	2.4	80.6%	80.6%	82.0%	86.0%	90.3%	80.6%	80.6%	80.6%	78.6%	11.7%
(2) Improvement over MCID	SRS22 MH	2.4	64.7%	64.7%	66.6%	72.4%	79.2%	64.7%	64.7%	64.7%	62.0%	17.2%
(1) Overall improvement	SRS22 pain	2	61.4%	63.7%	67.1%	76.2%	82.6%	61.4%	61.4%	61.4%	62.2%	21.2%
(2) Improvement over MCID	SRS22 pain	2	46.2%	48.6%	52.3%	62.9%	71.0%	46.2%	46.2%	46.2%	47.0%	24.8%
(1) Overall improvement	SRS22 SI	2.4	81.5%	81.5%	83.7%	84.3%	86.9%	81.5%	81.5%	81.5%	81.5%	5.4%
(2) Improvement over MCID	SRS22 SI	2.4	34.6%	34.6%	37.8%	38.8%	43.3%	34.6%	34.6%	34.6%	34.6%	8.7%
(1) Overall improvement	SRS22 subtotal	2.38	69.8%	72.1%	74.7%	84.8%	91.7%	69.8%	69.8%	69.8%	70.7%	21.9%
(2) Improvement over MCID	SRS22 subtotal	2.38	45.8%	48.4%	51.7%	65.6%	77.7%	45.8%	45.8%	45.8%	46.8%	31.9%
(1) Overall improvement	SF36v2 MCS	22.18	95.6%	95.4%	95.6%	97.0%	98.0%	95.6%	95.6%	95.6%	95.6%	2.6%
(2) Improvement over MCID	SF36v2 MCS	22.18	81.5%	81.0%	81.5%	85.9%	89.5%	81.5%	81.5%	81.5%	81.5%	8.5%
(1) Overall improvement	SF36v2 PCS	39.66	44.3%	45.3%	34.6%	60.4%	63.4%	44.3%	44.3%	44.3%	43.5%	28.8%
(2) Improvement over MCID	SF36v2 PCS	39.66	17.4%	18.0%	11.6%	29.7%	32.4%	17.4%	17.4%	17.4%	16.9%	20.8%

We present an accurate and consistent way of predicting outcome scores for ASD surgery in the largest-to-date prospective operative multicenter cohort with 2-year follow-up.

This study has significant clinical implications for shared-decision making, surgical planning and postoperative counseling.

Surgeon and site were important components of the model, explaining variance in predicted 2-yr HRQOL.

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