Establishing Minimum Clinically Important Difference in Physical Function, Mental Function, and Pain in Cervical Disc Replacement

James W. Nie, BS[1]; Timothy J. Hartman, MD[1]; Omolabake O. Oyetayo, BS[1]; Eileen Zheng, BS[1]; Keith R. MacGregor, BS[1]; Kern Singh, MD[1,2]

[1]Department of Orthopaedic Surgery, Rush University Medical Center

[2]Professor, Co-Director of the Minimally Invasive Spine Institute at Rush University Medical Center; Founder and President, Minimally Invasive Spine Study Group

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MISSG Minimally Invasive Spine Study Group

Midwest Orthopaedics at RUSH
Minimally Invasive Spine Institute

Background

The minimum clinically important difference (MCID) allows clinicians and researchers to determine clinically meaningful improvements in patient outcomes. MCID values for physical function, mental function, and pain has not been established in patients undergoing cervical disc replacement (CDR).

Objective

To establish MCID values in patients undergoing CDR through anchor- and distribution-based methods using the Neck Disability Index (NDI) as the anchor

Methodology: Data Collection

Inclusion Criteria	Exclusion Criteria
• Primary, elective CDR • Preoperative and 12-week postoperative NDI	• Revision surgery • Diagnosis of malignancy, trauma, or infection

Demographics	Preoperative	Intraoperative	Postoperative
• Age • Gender • Ethnicity • BMI • Hypertension • Smoking status • Diabetic status • Insurance coverage	• Charlson Comorbidity Index (CCI) • American Society of Anesthesiologists (ASA) classification • Spinal diagnosis	• Operative duration • Estimated blood loss	• Postoperative Length of stay • Postoperative VAS pain score • Postoperative narcotic consumption

MCID values were calculated for the following patient-reported outcome measures (PROMs):

- Patient-Reported Outcomes Measurement Information System Physical Function (PROMIS-PF)
- 12-Item Short Form Physical and Mental Composite Scores (SF-12 PCS/MCS)
- Veterans RAND-12 Physical Composite Score (VR-12 PCS)
- Visual Analog Scale (VAS) neck and arm

Methodology: Statistical Analysis

- Anchor-based
  - Average change
  - Minimal detectable change (MDC)
  - Change difference
  - Receiver operating characteristic (ROC) curve
    - Concordance probability method
    - Youden index
    - Closest to (0,1) criteria
  - Cross-sectional analysis

- Anchor: Neck Disability Index
- Responders: Postoperative improvement of ≥1 disability classification
- Non-responders: Postoperative worsening or no change in disability classification

- Distribution-based
  - Standard error of measurement
  - Reliable change index
  - Effect size

Results: Baseline and Perioperative Characteristics

- 156 patients were identified with a mean age of 48.7 years
- 84.0% presented with herniated disc
- 62.2% had 1-level CDR
- 80.8% presented with myeloradiculopathy

Table 1. Patient Demographics

Characteristic	Total (n= 156)
Age (mean ± SD, years)	48.7±9.2
Gender	
Female	43.6.4% (68)
Male	56.4% (88)
Ethnicity	
Caucasian	78.2% (122)
African-American	10.3% (16)
Hispanic	7.7% (12)
Asian	1.9% (3)
Other	1.9% (3)
BMI (mean ± SD, kg/m^2)	29.6±5.9
Comorbidities	
Smoker	13.5% (21)
Hypertension	24.4% (38)
Diabetes	10.3% (16)
ASA Classification	
<2	18.1% (23)
≥2	81.9% (104)
CCI Score (Mean ± SD)	1.2±1.3
Insurance Type	
Medicare/Medicaid	1.9% (3)
Workers' Comp	34.6% (54)
Private	63.5% (99)

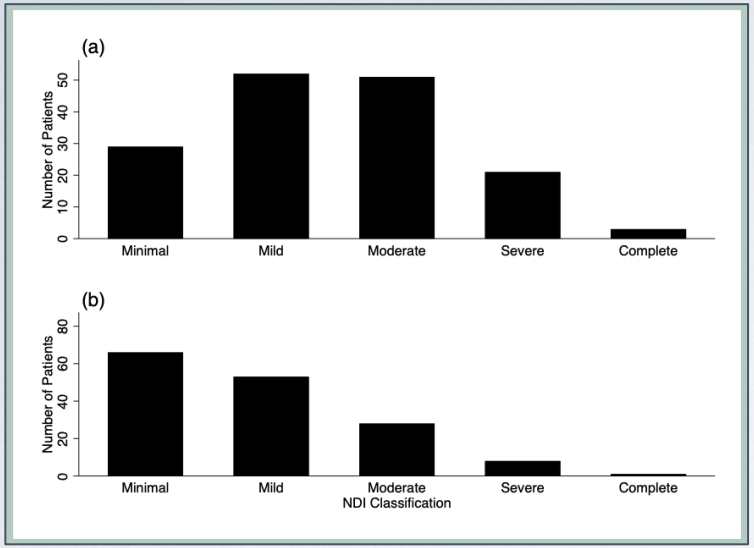
BMI = body mass index; CCI = Charlson Comorbidity Index; ASA = American Society of Anesthesiologists; SD= standard deviation; Workers' Comp = workers' compensation

Table 2. Perioperative Characteristics

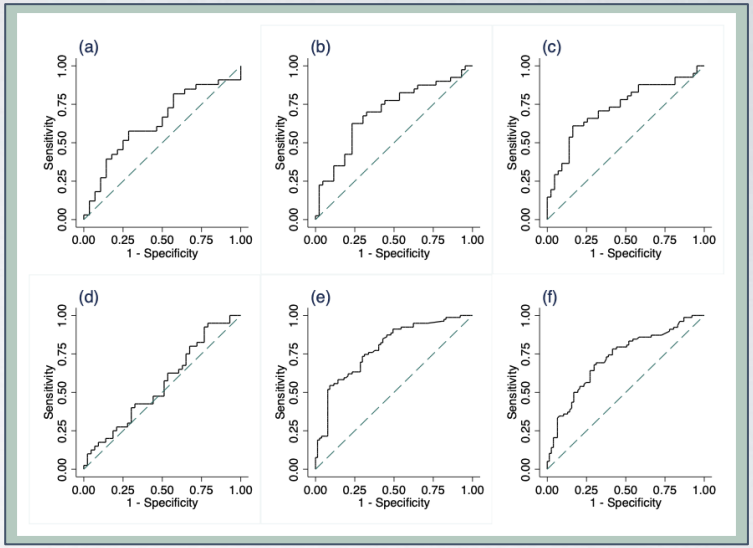
Characteristic	Total (n= 156)
Spinal Pathology	
Herniated Nucleus Pulposus	84.0% (131)
Degenerative Disc Disease	8.3% (13)
Central Stenosis	51.3% (80)
Foraminal Stenosis	7.7% (12)
Levels Treated	
One level	62.2% (97)
Two levels	37.8% (59)
Symptom Etiology	
Radiculopathy	18.0% (28)
Myelopathy	1.3% (2)
Myeloradiculopathy	80.8% (126)
Operative Time (Mean ± SD; min)	57.1±14.0
Estimated Blood Loss (Mean ± SD; mL)	28.4±10.0
Length of Stay (Mean ± SD; hours)	10.8±8.0
Acute Postoperative Vas Pain	
POD 0	4.9±2.1
POD 1	4.4±1.7
Postoperative Narcotic Consumption (OME)	
POD 0	37.6±26.9
POD 1	7.5±17.0

POD = postoperative day; mL = milliliters; SD = standard deviation; Vas = Visual analog scale; OME = oral morphine equivalents

Results: MCID Characteristics



Frequency of patients by (a) preoperative and (b) 12-week postoperative NDI classifications. There were 79 (50.6%) responders and 77 (49.4%) non-responders



ROC and area under curve (AUC) for (a) PROMIS-PF 0.65, (b) SF-12 PCS 0.70, (c) VR-12 PCS 0.72, (d) SF-12 MCS 0.55, (e) VAS neck 0.79, and (f) VAS arm 0.72

Results: MCID Values

- The minimum detectable change (MDC) was selected as the most appropriate set of MCID values, as this method accounted for:
  - Measurement error
  - Clinical relevance

Table 3. Minimal Clinically Important Difference Calculated Values

MCID Calculation	PROMIS-PF	SF-12 PCS	VR-12 PCS	SF-12 MCS	VAS Neck	VAS Arm
Anchor-based						
Average Change	7.8	7.9	9.1	5.2	4.4	4.3
MDC	**7.1**	**4.0**	**4.5**	**5.7**	**2.2**	**2.3**
Change Difference	3.6	6.5	6.8	3.1	2.8	2.7
ROC, CZ	6.1	5.5	7.9	0.2	3.0	*
ROC, *J*	6.1	5.5	7.9	-8.8	4.1	3.2
ROC, ER	6.1	5.5	7.9	0.2	3.0	3.2
ROC AUC	0.65	0.70	0.72	0.55	0.79	0.72
Cross-sectional	7.1	5.6	6.2	8.9	1.8	1.7
Distribution-based						
r	0.95	0.77	0.945	0.77	0.95	0.95
SEM	1.6	3.9	2.1	6.4	0.6	0.6
RCI	4.3	10.7	5.9	17.7	1.6	1.6
Effect Size	1.4	1.6	1.8	2.7	0.5	0.5

MDC = minimal detectable change; ROC = receiver operating curve; CZ = concordance probability method; *J* = Youden index; ER = closest to (0,1) criteria; AUC = area under curve; *r* = test-retest intraclass correlation coefficient of stable patients; SEM = standard error of measurement; RCI = reliable change index
*Multiple optimal cutoffs when using the concordance probability method.
Boldface indicates optimal MCID calculation method

Discussion / Conclusion

- Determined MCID values can vary widely depending on calculation method
- Use of the NDI anchor-based minimal detectable change method provided optimal MCID thresholds for patients undergoing CDR
- MCID values obtained were:

PROMIS-PF:	7.1	VR-12 PCS:	4.5
SF-12 PCS:	4.0	VAS Neck:	2.2
SF-12 MCS:	5.7	VAS Arm:	2.3