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The Influence of Multilevel Spinal Deformity Surgery on the EuroQol 5 Dimensions' (EQ-5D) Questionnaire and Residential Status in the Elderly: A Prospective, Observational, Multicenter Study

Thorsten Jentzsch, PD Dr. med. MSc[1,2,3], Stephen J. Lewis, MD, MSc, FRCSC[1],
Colby Oitment, MD, FRCSC[4], Anna Rienmüller, Dr. med. univ[5],
Allan R. Martin, MD, PhD, FRCSC[6], Christopher J. Nielsen, MD, FRCSC[1],
Hananel Shear-Yashuv, MD[7], Marinus de Kleuver, MD[8], Yong Qiu, MD[9],
Yukihiro Matsuyama, MD[10], Lawrence G. Lenke, MD[11], Ahmet Alanay, MD[12],
Ferran Pellisé-Urquiza, MD, PhD[13], Kenneth M. C. Cheung, MD, FRCS[14],
Maarten Spruit, MD[15], David W. Polly, MD[16], Jonathan N. Sembrano, MD[16],
Christopher I. Shaffrey, MD[17], Justin S. Smith, MD[18], Michael P. Kelly, MD[19],
Benny Dahl, MD[20,21], Sigurd H. Berven, MD[22], and AO Spine Knowledge Forum Deformity

Abstract

Study Design: Multicenter, international prospective study.

[1] Division of Orthopaedic Surgery, Arthritis Program, Toronto Western Hospital, University Health Network, Toronto, ON, Canada
[2] Department of Surgery, University of Toronto, Toronto, ON, Canada
[3] Department of Orthopaedics, University of Zurich, Balgrist University Hospital, Zurich, Switzerland
[4] Division of Orthopaedic Surgery, Department of Surgery, McMaster University, Hamilton, ON, Canada, Canada
[5] Department of Orthopedic and Trauma Surgery, Medical University Vienna, Vienna, Austria
[6] Department of Neurological Surgery, University of California - Davis, Sacramento, CA, USA
[7] Department of Orthopaedic, Hebrew University, Hadassah Medical Center, Jerusalem, Israel
[8] Department of Orthopedics, Medical Center, Radboud University, Nijmegen, Gelderland, The Netherlands
[9] Spine Surgery, Drum Tower Hospital of Nanjing University Medical School, Nanjing, Jiangsu, China
[10] Department of Orthopedic Surgery, Hamamatsu University School of Medicine, Hamamatsu, Shizuoka, Japan
[11] Department of Orthopedic Surgery, The Spine Hospital, Medical Center, Columbia University, New York, NY, USA
[12] Department of Orthopedics and Traumatology, Acibadem Mehmet ali Aydinlar University, Istanbul, Turkey
[13] Hospital Universitari de la Vall d'Hebron, Barcelona, Spain
[14] Department of Orthopaedics and Traumatology, The University of Hong Kong, Hong Kong
[15] Sint Maartenskliniek Nijmegen, Gelderland, the Netherlands
[16] Department of Orthopaedic Surgery, University of Minnesota, Minneapolis, MN, USA
[17] Department of Orthopaedic Surgery, Duke University, Durham, NC, USA
[18] Department of Neurosurgery, University of Virginia, Charlottesville, VA, USA
[19] Orthopaedic Surgery, Washington University School of Medicine, St Louis, MO, USA
[20] Division of Orthopedic Surgery, Texas Children's Hospital and Baylor College of Medicine, Houston, TX, USA
[21] Spine Unit, Rigshospitalet, University of Copenhagen, Denmark
[22] Department of Neurosurgery and Orthopaedic Surgery, University of California, San Francisco, CA, USA

Corresponding Author:
Stephen J. Lewis, Division of Orthopaedic Surgery, Arthritis Program, Toronto Western Hospital, University Health Network, 399 Bathurst St, 1E442, Toronto, ON M5G 2C4, Canada.
Email: stephen.lewis@uhn.ca

Objective: This study investigated the clinical outcome up to 2 years after multi-level spinal deformity surgery in the elderly by reporting the minimal clinically important difference (MCID) of EuroQol 5-dimensions (EQ-5D), EQ-VAS, and residential status.

Methods: As an ancillary study of 219 patients ≥60 years with spinal deformity undergoing primary instrumented fusion surgery of ≥5 levels, this study focuses on EQ-5D (3-L) as the primary outcome and EQ-VAS and residential status as secondary outcomes. Data on EQ-5D were compared between pre-operatively and postoperatively at 10 weeks, 12 months, and 24 months. An anchor-based approach was used to calculate the MCID.

Results: The EQ-5D index and EQ-VAS, respectively, improved significantly at each time point compared to pre-operatively (from .53 (SD .21) and 55.6 (SD 23.0) pre-operatively to .64 (SD .18) and 65.8 (SD 18.7) at 10 weeks, .74 (SD .18) and 72.7 (SD 18.1) at 12 months, and .73 (SD .20) and 70.4 (SD 20.4) at 24 months). 217 (99.1%) patients lived at home pre-operatively, while 186 (88.6%), 184 (98.4%), and 172 (100%) did so at 10 weeks, 12 months, and 24 months, respectively. Our calculated MCID for the EQ-5D index at 1 year was .22 (95% CI .15-.29).

Conclusions: The EQ-5D index significantly increased at each time point over 24 months after ≥5 level spinal deformity surgery in elderly patients. The MCID of the EQ-5D-3 L was .22. Patients living at home pre-operatively can expect to be able to live at home 2 years postoperatively.

Introduction

According to the United Nations, the number of elderly persons over 60 years of age had more than doubled within the past 4 decades to 982 million in 2017.[1] Alongside, the prevalence of adult spinal deformity is increasing. The rate of scoliosis in the elderly has been reported to be as high as 68%.[2] The non-surgical and surgical treatment strategies are still debated.[3] Therefore, it is important to study the clinical outcomes after each treatment strategy.

Patient-reported outcome measures (PROMs), such as the Scoliosis Research Society- (SRS-) 22r or Oswestry Disability Index (ODI) are often disease-specific and do not allow comparison with other diseases through the calculation of a single utility value and quality-adjusted life years (QALYs).[4] Other PROMs, such as the Short Form- (SF-) 36 and -12, are disease-non-specific, but also do not allow calculation of QALYs and are time-consuming for patients to complete.[5] The EuroQol 5 dimensions' questionnaire (EQ-5D) is a shorter questionnaire allowing calculation of a single utility score for QALYs and, to a certain extent, can actually be predicted from the SRS-22r,[6] ODI,[7] and the SF-12.[8] It has become a commonly used, validated, standardized, generic (disease-non-specific) PROM that is even required for economic evaluation by the National Institute for Health and Care Excellence (NICE).[6,9,10] It was designed in 1990 and the current version has been used for more than 10 years. It is also important to know the minimal clinically important difference (MCID) of the EQ-5D, which is the smallest relevant change for a specific disease, in order to interpret the results.[11-15] Thus, the EQ-5D could potentially be a quick way to assess the health-related quality of life (HRQOL) after

spinal deformity surgery and allow comparison with other disease entities.

There are very limited studies[16-23] regarding the clinical outcome focusing on the EQ-5D and, to the best of our knowledge, no studies related to the MCID and residential status before and after multilevel spinal deformity surgery in the elderly. This study aimed to investigate the clinical outcome by providing an in-depth analysis of the EQ-5D and, to a lesser degree, the residential status up to 24 months after ≥5 level spinal deformity surgery in patients ≥60 years of age. A comparison of our data to the literature was undertaken regarding similar patient cohorts[16-24] and common diseases (e.g., coronary artery disease[25]).[26] The hypotheses were that the EQ-5D significantly improves after multilevel deformity surgery in the elderly with a certain MCID and that most of these patients reside at home 2 years postoperatively.

Materials and Methods

Study Design

The main methods and results of this study have been previously reported elsewhere.[27] This study focuses on the EQ-5D-3 L as the primary outcome and residential status as the secondary outcome. In brief, 12 different international centers prospectively enrolled 255 patients ≥60 years with spinal deformity undergoing primary instrumented fusion surgery of ≥5 levels after obtaining ethics approval from the Institutional Review Boards (Supplementary Table 0) and informed consent from patients. In this series, deformity was defined as any degenerative thoracic or lumbar spinal pathology that required fusion of greater than or equal to 5

levels. Surgeons were free to choose indications and surgical technique based on their current standard of practice. Exclusion criteria were previous surgery (except decompression ≤2 levels), neurodegenerative disease or paralysis, non-compliance, institutionalization or imprisonment, being medically unfit, recent substance abuse, interfering psychiatric disease, active tumor or infection, recent spinal tumor or fracture, participation in related trials.

The EQ-5D-3 L, with 3 levels of severity for each dimension, was chosen due to this being the most widely used version.[28] The 5 dimensions are mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.[29] They are categorized as no problems, some problems, and extreme problems. They can be converted into a single number from worst health (33 333) to best health (11 111). This number can be transformed into a single summary index value from 0 (dead) to 1 (best health) with the aid of a value set, which depended on US population norms in our study. The EQ-VAS assesses the health state by asking patients to grade their health from 0 (worst) to 100 (best).

Ethics approval was given at each site. Informed consent was obtained from all patients. A central contracted research organization (CRO) gathered all forms and radiographs. The trial was registered at clinicaltrails.gov (NCT02035280).

Statistics

Descriptive statistics were used to represent demographic and EQ-5D data (mean and standard deviation (SD) or median and interquartile range (IQR) for continuous variables; absolute number and frequency for categorical variables) preoperatively as well as postoperatively at 10 weeks (±6 weeks), 12 months (±2 months), and 24 months (±2 months). A sensitivity analysis on patients who have completed EQ-5D assessment at each timepoint was performed to verify the results. An unadjusted and adjusted mixed effects linear regression model with an unstructured covariance at patient level with a Wald test on change in least-square means to pre-operative value was performed. The adjusted model accounted for age, BMD, Charlson comorbidity score, depression and pre-operative cognitive impairment indication by animal fluency test. For 2 patients, who passed away within 24 months after surgery due to related adverse events, the EQ-5D index for subsequent time points was inputted as 0 (=death), but the EQ-5D items and the EQ-VAS data were not included. There were few missing data and a case approach was undertaken. The amount of missing data are provided in the tables. Furthermore, EQ-5D scores were grouped into improvement from baseline (substantial (≥20% of EQ-5D range) and marginal (≥10-<20%)), similarity to baseline (within 10%), and decrease from baseline (marginal (≥10-<20%) and substantial (≥20%)). Patients were also grouped in 5-year increments age classes (i.e., 60-64, 65-69, 70-74, and ≥75 years).

As anchors for the MCID calculation at 1 year, 2 items of SRS-22r questionnaire related to satisfaction with the results of the back management (1-very unsatisfied, 2-unsatisfied, 3-neither satisfied nor unsatisfied, 4-satisfied, 5-very satisfied) and willingness to undergo the same management again (1-definitely not, 2-probably not, 3-not sure, 4-probably yes, 5-definitely yes) were defined. The time point of 1 year was chosen for better comparisons with previous MCID calculations, as done for patients with degenerative lumbar spinal stenosis.[12] The points of both items were summarized and grouped into worsening (2-3 points), slight worsening (4-5 points), no change (6 points), slight improvement (7-8 points), and improvement (9-10 points). Afterwards, for the MCID calculation, descriptive statistics of EQ-5D index preoperatively, 1 year and the change to preoperatively were presented. . The MCID is given as the mean value of the change to preoperative value of the slight improvement group. The significance level was defined as $P ≤ .05$. All analyses were performed using SAS 9.4 (SAS Institute, Cary, North Carolina, United States of America).

Results

Participants

219 patients met the inclusion and exclusion criteria. 32 patients dropped out (14 withdrew consent, 13 were lost to follow-up, and 5 died). Two deaths were related to the study intervention (cardiac arrest 1 day postoperatively and deep vein thrombosis 9 days postoperatively and subsequent cardiac arrest). The other 3 deaths were unrelated to the study intervention (death while sleeping, pancreatic cancer, carcinoma). 214 (97.7%) and 207 (94.5%) completed the EQ-5D index and EQ-5D VAS pre-operatively, 205 (93.6%) each completed it at 10 weeks, 187 (85.4%) and 183 (83.6%) completed it at 12 months, and 177 (80.8%) and 171 (78.1%) completed it at 24 months. 219 patients filled out the residential status pre-operatively, while 210 (95.9%), 187 (85.4%), and 172 (78.5%) did so after 10 weeks, 12 months, and 24 months, respectively.

The mean age of the study population was 67.5 (SD 5) years, 176 (80%) were female, and the median number of levels fused was 9 (IQR 8-14). The mean body mass index was 26.1 (SD 5), the majority of patients had American Society of Anesthesiologists (ASA) scores of II (61%) and III (34%), and the mean Charlson Comorbidity Index (CCI) was .5 (SD .8). The most common Charlson comorbidity index item was diabetes (n = 22 (10.0%), followed by chronic pulmonary disease (n = 16 (7.3%)), moderate or severe renal disease (n = 9 (4.1%)), peripheral vascuar disease (n = 7 (3.2%)), cerebrovascular disease (n = 6 (2.7%)), ulcer diseease (n = 6, (2.7%)), any tumor (n = 5 (2.3%)), connective tissue disease (n = 5 (1.8%)), myocardial infarct (n = 3 (1.4%)), mild liver disease (n = 2 (.9%)), diabetes with end organ damage (n = 1 (.5%)), dementia (n = 1 (.5%)), and moderate or severe liver

disease (n = 1 (.5%)). The most common surgical approach was a posterior (n = 168 (76.7%)), followed by anterior/lateral (n = 45 (20.6%)), and combined posterior with anterior/lateral (n = 6 (2.7%)). The mean fused levels were 8.9 (SD 4.8). The mean duration of surgery was 407 minutes (interquartile range 330-476). The mean thoraco-lumbar Cobb angle was 31.9° (SD 23.6°, minimum (min) 1.7°, maximum (max) 102.5°), the sagittal vertical axis was 91.9 mm (SD 74.2 mm, min -76.3 mm, max 327.2 mm), and the pelvic incidence minus lumbar lordosis was 28° (SD 21°, min -25.9°, max 86.3°).[30]

Main Outcome (EQ-5D)

The mean EQ-5D index and mean EQ-VAS increased at each time point (from .53 (SD .21) and 55.6 (SD 23.0) pre-operatively to .64 (SD .18) and 65.8 (SD 18.7) at 10 weeks, .74 (SD .18) and 72.7 (SD 18.1) at 12 months, and remained as .73 (SD .20) and 70.4 (SD 20.4) at 24 months. These changes remained similar in the sensitivity analysis (Supplementary Table 1).

The EQ-5D showed improvements from pre-operatively to post-operatively across almost all dimensions (Table 1) except for self-care and usual activities at 10 weeks. While substantial improvements were made from pre-operative to 10 weeks and to 12 months, similar outcome scores were observed at the 12 and 24 months follow ups. No problems in mobility was reported by 20 (9.3%) patients pre-operatively, 46 (22.0%) patients at 10 weeks, 86 (46.0%) patients at 12 months, and 73 (41.2%) at 24 months. No problems in self-care was reported by 124 (57.7%) patients pre-operatively, 62 (29.8%) patients at 10 weeks, 115 (61.5%) patients at 12 months, and 109 (61.6%) at 24 months. No problems in usual activities was reported by 18 (8.4%) patients pre-operatively, 8 (3.9%) patients at 10 weeks, 62 (33.2%) patients at 12 months, and 57 (32.2%) at 24 months. No pain/discomfort was reported by 5 (2.3%) patients pre-operatively, 37 (18.0%) patients at 10 weeks, 53 (28.6%) patients at 12 months, and 55 (31.4%) at 24 months. No anxiety/depression was reported by 88 (40.9%) patients pre-operatively, 130 (62.8%) patients at 10 weeks, 130 (69.5%) patients at 12 months, and 128 (72.3%) at 24 months. These changes remained similar in the sensitivity analysis (Figure 1, Supplementary Table 2).

As observed in the unadjusted data (Table 2), the adjusted EQ-5D index and EQ-VAS (95% confidence interval (CI)), respectively, increased significantly at each time point compared to pre-operatively (i.e., .52 (95% CI .48-.56) and 53.7 (95% CI 49.5-58.0) points pre-operatively, .64 (95% CI .61-.68) and 64.5 (95% CI 60.8-68.3) points at 10 weeks, .75 (95% CI .71-.78) and 73.5 (95% CI 69.9-77.0) points at 12 months, as well as .73 (95% CI .69-.77) and 70.3 (95% CI 66.4-74.3) points at 24 months; $P < .001$ each) (Table 3). The overall changes for the adjusted EQ-5D index and EQ-VAS from pre-operatively to 24 months were .21 (95% CI .17-.25) and 16.6 (95% CI 12.1-21.0) points.

The EQ-5D index improved substantially in 80 (46.5%) patients and marginally in 22 (12.8%)), remained similar in 53 (30.8%), and decreased marginally in 10 (5.8%), and substantially in 7 (4.1%)) (Table 4).

The unadjusted EQ-5D index were significantly better at each postop time point vs pre-operatively for each age class except for the subgroup of patients ≥75 year old at the 10 week follow up visit. The EQ-VAS had similar improvements at all postop time points in the patients with the exception of the subgroup of patients ≥75 years, who did not show significant improvements compared to baseline at any of the follow-up visits. (Table 5).

The MCID for the EQ-5D index at 1 year calculated for our patient population was .22 (95% CI .15-.29) (Supplementary Tables 3-5).

EQ-5D in Comparison to Other PROMS

Improvements were seen in all PROMS in this cohort. From pre-operative to 24 months post-operative, the overall mean EQ-5D index improved by 20% and the EQ-VAS improved by 15%. In comparison, the SRS-22r total improved by 18% (2.8 to 3.7 points), the ODI by 19% (46% to 27%), the NRS back improved by 34% (2.7 to 6.1), and the NRS leg improved by 20% (2.3 to 4.3).

Residential Status

217 (99.1%) patients lived at home pre-operatively, while 186 (88.6%), 184 (98.4%), and 172 (100%) did so at 10 weeks, 12 months, and 24 months, respectively (Table 6).

Discussion

In this multicenter, international, prospective study of patients ≥60 years with spinal deformity undergoing primary instrumented fusion surgery of ≥5 levels, the EQ-5D index significantly increased at each time point. The mean EQ-5D index and mean EQ-VAS improved from .53 and 55.6 points pre-operatively, to .74 and 72.7 at 12 months and .73 and 70.4 points at 24 months. At 24 months, the majority of patients scored their disability as mild or moderate, with very few patients grading their disabilities as severe. Most extreme problems were found in usual activities and pain/discomfort, where 8.6% of patients were unable to perform usual activities and 6.8% had extreme pain/discomfort at 24 months. Despite this, the patients in this cohort had significantly lower baseline index scores than those seen in chronic diseases that include stroke, heart failure, diabetes, and angina. Worsening of the EQ-5D at 24 months was observed in only a few patients (i.e., 9.9%, of which 4.1% was categorized as substantial worsening). The calculated MCID for the EQ-5D index was .22, which appears to be the first calculation for these patients with multilevel surgery for degenerative scoliosis. While most patients (i.e., 88.6%)

Table I. EuroQol 5 Dimensions' (EQ-5D) Over the Course of Follow-Up.

	Visit			
	Pre-Operative	10 Weeks	12 Months	24 Months
Variable	N = 219	N = 211	N = 190	N = 181
Mobility, N (%)	215	209	187	177
I have no problems in walking about	20 (9.3)	46 (22.0)	86 (46.0)	73 (41.2)
I have some problems in walking about	188 (87.4)	162 (77.5)	101 (54.0)	104 (58.8)
I am confined to bed	7 (3.3)	1 (.5)	0 (.0)	0 (.0)
Self-care, N (%)	215	208	187	177
I have no problems with self-care	124 (57.7)	62 (29.8)	115 (61.5)	109 (61.6)
I have some problems washing or dressing myself	87 (40.5)	137 (65.9)	71 (38.0)	66 (37.3)
I am unable to wash or dress myself	4 (1.9)	9 (4.3)	1 (.5)	2 (1.1)
Usual activities, N (%)	214	207	187	177
I have no problems with performing my usual activities	18 (8.4)	8 (3.9)	62 (33.2)	57 (32.2)
I have some problems with performing my usual activities	167 (78.0)	157 (75.8)	117 (62.6)	106 (59.9)
I am unable to perform my usual activities	29 (13.6)	42 (20.3)	8 (4.3)	14 (7.9)
Pain/discomfort, N (%)	215	206	185	175
I have no pain or discomfort	5 (2.3)	37 (18.0)	53 (28.6)	55 (31.4)
I have moderate pain or discomfort	115 (53.5)	155 (75.2)	123 (66.5)	107 (61.1)
I have extreme pain or discomfort	95 (44.2)	14 (6.8)	9 (4.9)	13 (7.4)
Anxiety/depression, N (%)	215	207	187	177
I am not anxious or depressed	88 (40.9)	130 (62.8)	130 (69.5)	128 (72.3)
I am moderately anxious or depressed	107 (49.8)	68 (32.9)	53 (28.3)	45 (25.4)
I am extremely anxious or depressed	20 (9.3)	9 (4.3)	4 (2.1)	4 (2.3)

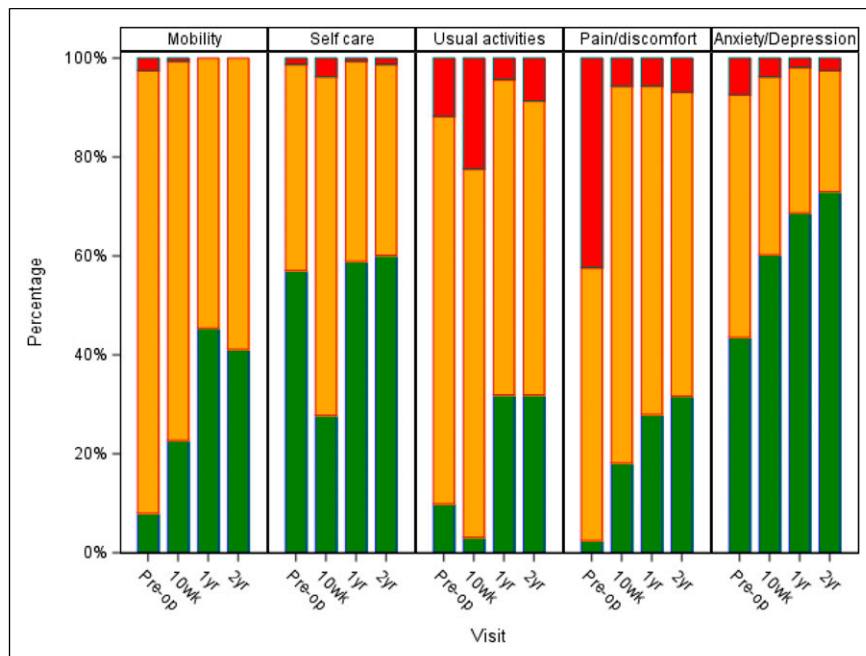Abbreviations: N (absolute number); % (percent).

Figure 1. Stacked bar chart of the EuroQol 5 dimensions' (EQ-5D) dimensions as sensitivity analysis on patients with complete data pre-operatively (pre-op) and during follow-up visits at ten weeks (wk), 1 year (yr), and 2 years (N = 163).

Table 2. Changes in EuroQol Visual Analogue Scale (EQ-VAS) and 5 Dimensions' (EQ-5D) Index Over the Course of Follow-Up; Unadjusted Mixed-Effects Modeling.

Variable	Visit	N	Mean (95% CI)	Change (95% CI) to Pre-Operative	P Value
EQ-5D index	Pre-operative	214	.53 (.50; .56)		
	10 weeks	205	.64 (.62; .67)	.11 (.08; .15)	<.001
	12 months	187	.74 (.72; .77)	.21 (.18; .25)	<.001
	24 months	177	.73 (.70; .76)	.20 (.17; .23)	<.001
EQ-VAS	Pre-operative	207	55.7 (52.6; 58.9)		
	10 weeks	205	65.8 (63.2; 68.3)	10.1 (6.5; 13.6)	<.001
	12 months	183	72.8 (70.2; 75.4)	17.1 (13.4; 20.8)	<.001
	24 months	171	70.0 (67.0; 73.0)	14.3 (10.6; 18.1)	<.001

Note: Results from a mixed-effects linear regression model with an unstructured covariance (patient level). P-values were calculated using the Wald test. Abbreviations: N (absolute number); % (percent); CI (confidence interval).

Table 3. Changes in EuroQol Visual Analogue Scale (EQ-VAS) and 5 Dimensions' (EQ-5D) Index Over the Course of Follow-Up; Adjusted Mixed-Effects Modeling.

Variable	Visit	N	Mean (95% CI)	Change (95% CI) to Pre-Operative	P-Value
EQ-5D index	Pre-operative	150	.52 (.48; .56)		
	10 weeks	141	.64 (.61; .68)	.13 (.08; .17)	<.001
	12 months	128	.75 (.71; .78)	.23 (.19; .27)	<.001
	24 months	121	.73 (.69; .77)	.21 (.17; .25)	<.001
EQ-VAS	Pre-operative	147	53.7 (49.5; 58.0)		
	10 weeks	140	64.5 (60.8; 68.3)	10.8 (6.5; 15.1)	<.001
	12 months	125	73.5 (69.9; 77.0)	19.8 (15.4; 24.1)	<.001
	24 months	115	70.3 (66.3; 74.3)	16.6 (12.1; 21.0)	<.001

Note: Results from a mixed-effects linear regression model with an unstructured covariance (patient level) after adjusting for age, BMD, Charlson comorbidity score, depression and pre-operative cognitive impairment indication by animal fluency test. P-values were calculated using the Wald test. Abbreviations: N (absolute number); % (percent); CI (confidence interval).

Table 4. EuroQol 5 Dimensions' (EQ-5D) Index Change to Pre-Operative Over the Course of Follow-Up.

	Visit		
	10 weeks	12 months	24 months
Variable	N = 212	N = 190	N = 181
Change in EQ-5D index to pre-operative, N (%)	200	182	172
Improvement (≥20%)	71 (35.5)	97 (53.3)	80 (46.5)
Improvement (≥10% and <20%)	24 (12.0)	17 (9.3)	22 (12.8)
No change (≥-10% and <10%)	70 (35.0)	55 (30.2)	53 (30.8)
Worsening (≥-20% and <-10%)	17 (8.5)	5 (2.7)	10 (5.8)
Worsening (<-20%)	18 (9.0)	8 (4.4)	7 (4.1)

Note: Change in EQ-5D index was calculated based of 10%, 20% change of the total EQ-5D range (0-1). This means 10% change is a change of .1 points in EQ-5D index. Furthermore, different number of patients are given because a few patients did not have a pre-operative or follow-up EQ-5D index, entailing missing data. Abbreviations: N (absolute number); % (percent).

lived at home after 10 weeks, most patients (98.4%) lived at home after 12 months and all surviving patients that reported for follow-up at 24 months lived at home.

The EQ-5D provides a quick disease-non-specific measuring instrument that allows calculation of QALYs and comparison to other diseases. This is a potential benefit over the SRS-22r and SF-12.[4,5] A previous study by Wong et al[6] has shown that around 62% of variance of the EQ-5D can be predicted by the SRS-22r in patients with adolescent idiopathic scoliosis. In our study the EQ-5D index and EQ-VAS showed similar postoperative improvements (20% and 15%, respectively) to the SRS-22r (18%) and ODI (19%),

Table 5. Changes in EuroQol Visual Analogue Scale (EQ-VAS) and 5 Dimensions' (EQ-5D) Index Over the Course of Follow-Up After Unadjusted Mixed Effects Modeling for Age Class.

Variable	Age Class	Visit	N	Mean (95% CI)	Change (95% CI) to Pre-Operative	P-Value
EQ-5D index	60-64	Pre-operative	79	.53 (.48; .58)		
		10 weeks	73	.66 (.62; .70)	.13 (.07; .19)	<.001
		12 months	66	.76 (.72; .81)	.23 (.17; .29)	<.001
		24 months	60	.70 (.65; .75)	.17 (.11; .23)	<.001
	65-69	Pre-operative	62	.52 (.46; .57)		
		10 weeks	63	.66 (.62; .70)	.14 (.08; .21)	<.001
		12 months	55	.73 (.68; .77)	.21 (.14; .28)	<.001
		24 months	54	.74 (.69; .79)	.22 (.16; .28)	<.001
	70-74	Pre-operative	46	.52 (.46; .58)		
		10 weeks	43	.62 (.57; .67)	.10 (.02; .17)	.011
		12 months	43	.74 (.69; .79)	.22 (.14; .29)	<.001
		24 months	41	.75 (.69; .81)	.23 (.15; .30)	<.001
	≥75	Pre-operative	27	.56 (.48; .64)		
		10 weeks	26	.58 (.51; .65)	.02 (-.08; .12)	.690
		12 months	23	.73 (.66; .80)	.17 (.07; .27)	.001
		24 months	22	.73 (.66; .81)	.17 (.08; .27)	<.001
EQ-VAS	60-64	Pre-operative	78	51.2 (46.2; 56.3)		
		10 weeks	74	67.1 (62.8; 71.4)	15.8 (10.1; 21.6)	<.001
		12 months	66	76.4 (72.2; 80.7)	25.2 (19.3; 31.1)	<.001
		24 months	58	70.6 (65.4; 75.7)	19.3 (13.1; 25.6)	<.001
	65-69	Pre-operative	61	54.2 (48.5; 59.8)		
		10 weeks	62	63.9 (59.2; 68.6)	9.7 (3.3; 16.1)	.003
		12 months	54	67.8 (63.1; 72.5)	13.7 (7.0; 20.3)	<.001
		24 months	54	69.6 (64.2; 75.0)	15.4 (8.7; 22.2)	<.001
	70-74	Pre-operative	43	58.8 (52.0; 65.5)		
		10 weeks	42	66.8 (61.1; 72.5)	8.0 (.3; 15.7)	.042
		12 months	40	72.2 (66.7; 77.7)	13.5 (5.6; 21.3)	<.001
		24 months	38	68.3 (61.9; 74.8)	9.6 (1.5; 17.6)	.020
	≥75	Pre-operative	25	68.4 (59.5; 77.2)		
		10 weeks	27	65.0 (57.9; 72.1)	-3.4 (-13.3; 6.5)	.501
		12 months	23	75.4 (68.2; 82.7)	7.1 (-3.2; 17.3)	.178
		24 months	21	72.6 (63.9; 81.2)	4.2 (-6.5; 14.9)	.439

Note: Results from a mixed-effects linear regression model with an unstructured covariance (patient level). P-values were calculated using the Wald test. Abbreviations: N (absolute number); % (percent); CI (confidence interval).

Table 6. Residential Status Over the Course of Follow-Up.

	Visit			
	Pre-Operative	10 Weeks	12 Months	24 Months
Variable	N = 219	N = 212	N = 190	N = 181
Residential status, N (%)	219	210	187	172
Home	217 (99.1)	186 (88.6)	184 (98.4)	172 (100.0)
Residential care (assisted living)	2 (.9)	3 (1.4)	2 (1.1)	0 (.0)
Nursing home (constant medical supervision)	0 (.0)	2 (1.0)	0 (.0)	0 (.0)
Rehabilitation center	0 (.0)	19 (9.0)	1 (.5)	0 (.0)

Abbreviations: N (absolute number); % (percent).

which could indicate that it is a useful tool in assessing HRQOL of patients with adult spinal deformity. Being a much shorter and quicker questionnaire for patients to complete makes it appealing.

In order to understand the reported EQ-5D values for the reported cohort, it is important to understand the general risk of death in the elderly and to know normal values and scores for various chronic conditions. According to Statistics

Canada, the mortality annual rate per 1'000 population was 7.2 for age group 60-64 years, 11.1 for age group 65-69 years, 17.2 for age group 70-74 years, 29.0 for age group 75-79 years, 50.6 for age group 80-84 years, 91.5 for age group 85-89 years, 190.4 for age group>90 years in 2018.[31] Janssen et Szende reported EQ-5D index population norms for several countries/regions and age groups.[32] Using European VAS value sets, the values ranged from .69 (Armenia, 5 regions) to .95 (China) for the total of all age groups, .52 (Armenia, 5 regions) to .93 (Canada, Alberta) for the 65-74 age group and .47 (Armenia) to .87 (Canada) for the ≥75 age group. Using country-specific TTO (time trade-off) value sets, the values ranged from .83 (Zimbabwe, Harare district) to .96 (Korea) for the total of all age groups, .66 (Zimbabwe) to .90 (Italy) for the 65-74 age group and .59 (Spain, Catalunya) to .84 (Germany and Italy) for the ≥75 age group. Mean EQ-VAS scores ranged from 70 (Hungary) to 83 (Denmark). Furthermore, a population-based study by Diarbakerli et al[33] reported normative data for individuals ≥60 years. The EQ-5D 3-L index ranged around .87 in the United Kingdom and .93 in Sweden.

It appears that the current study is 1 of the first calculations of the MCID regarding the EQ-5D for patients with multilevel surgery for degenerative scoliosis. Since the EQ-5D is a quick assessment tool that allows the comparison with other diseases, it is important to know the MCID for the EQ-5D in addition to the previously known MCID for the SRS-22r[34,35] in adult spinal deformity. Although Ibrahim stated that 41% of 101 patients >70 years with ≥5 level fusion surgery reached the EQ-5D MCID of .15 at 2 years, the MCID value was based on lumbar revision surgery for pseudarthrosis.[14] Despite the fact that a study by Passias et al[36] reported that 19% of 63 patients after cervical deformity correction reached the EQ-5D MCID of .1 at 1 year, they based their MCID value on patients with post-traumatic stress disorder.[37] There is previous literature on the MCID on degenerative lumbar spinal stenosis with a value of .19 (range, .30-.52) as described by Burgstaller et al.[12] The MCID for other spine-related diseases ranged around .14-.24 for symptomatic pseudarthrosis,[14] .27-.54 for adjacent-segment disease,[13] and .17 for chronic low back pain.[15] The presented MCID for the EQ-5D index at 1 year was .22 in patients >60 years undergoing ≥5 level spinal deformity fusion surgery.

The mean EQ-5D has also been reported for other common diseases and varies across different regions.[26,38,39] For example, a study by Sullivan et Ghushchyan reported several EQ-5D index mean and median scores for chronic diseases in the United States. For example, diabetes mellitus (.751) had higher EQ-5D index scores than depression (.732), renal failure (.651), and heart failure (.636) in middle aged and elderly populations (Table 5).[38] The EQ-5D of .74 at the final follow-up in our study is in line with these results and slightly better than other musculoskeletal diseases in the UK and Japan (Supplementary Table 6).

There are a few studies that have previously reported similar EQ-5D values on similar patient cohorts after multilevel fusion surgeries for deformity. None of the cited studies, except the presented paper mentioned which level (3-L or 5-L) or the EQ-5D is used making comparisons difficult. The range of EQ-5D index and EQ-5D VAS improvement at 2 years was .35-.6 and 32-33, respectively.[16-20] Butler et al[16] retrospectively reviewed 178 patients with ≥2 level fusion surgeries using anterior lumbar interbody fusion (ALIF). They found an improvement in EQ-5D index and EQ-VAS, respectively, from .2 (SD .2) and 45 (SD 19.8) pre-operatively to .8 (SD .1) ($P = .06$) and 78 (SD 19) at 2 years ($P = .02$). Sabou et al[17] retrospectively evaluated 82 patients, respectively, with ≥2 level fusion surgeries to compare patients undergoing multilevel posterior lumbar interbody fusion (MPLIF) and MPLIF + anterior longitudinal ligament release (ALLR). The EQ-5D index improved from .20 (±.35) to .61 (±.23) for MPLIF and .19 (±.30) to .59 (±.34) in the MPLIF + ALLR group. Eskilsson et al[18,19] retrospectively investigated 76 patients years with multi-level fusion and pedicle subtraction osteotomies (PSO). They found an improvement in EQ-5D from .21 to .56. Molloy et al[20] prospectively reviewed 64 patients with mostly (91%) multi-level fusions describing a new extensile anterolateral retroperitoneal approach for interbody fusions in 360-degree procedures. The EQ-5D index and EQ-VAS, respectively, improved from .3 (.1) and 58 (6) pre-operatively to .8 (±.1) and 90 (±7) at 1 year (Table 7). Larger preoperative EQ-5D values and improvements in the EQ-5D index and -VAS may be due to the fact that previously operated patients were excluded and smaller deformities were included. The presented study adds valuable information to the literature as it was done in a prospective, multicenter fashion providing the largest sample size to date. In contrast to the studies mentioned above, the pre-operative values for the EQ-5D index and EQ-VAS were substantially higher (.53 and 56, respectively), allowing for a somewhat smaller improvement at 2 years follow-up.

In addition to the previous studies, the following studies also reported on similar topics. Cheng et Gerdhem[23] retrospectively analyzed 209 patients with a mean age of 66 years with lumbar fusion surgery to compare single-level (n = 45) vs ≥2-level (n = 164) fusions. They reported that the EQ-5D improved significantly in both groups at 2 years. They did not provide absolute values, but according to a box plot figure, the median EQ-5D index was approximately .15 pre-operatively and .65 for the multi-level group at 2 years. Li et al[24] retrospectively followed up on 83 patients with a mean age of 75 (range 65-88) years with a mean of 7 (±2) level fusion surgeries at a mean follow-up of approximately 2.5 years. No pre-operative EQ-5D values were provided. The EQ-5D was significantly better in the operative group (.79 (±.16)) than the conservative group (.67 (±.19)). The EQ-VAS showed a trend toward being better in the operative group (79 (±18)) than the conservative group (68 (±20)). In addition to these studies, Ibrahim et al[21] retrospectively studied 101 patients >70 years with ≥5 level fusion surgeries. They reported an improvement in HRQOL of at least 1 MCID (using .15) in the EQ-5D in

Table 7. EuroQol 5 Dimensions' (EQ-5D) Index and EQ-VAS in the Literature.

Authors	Patients	Age		Fused Levels				EQ-5D									
									Pre-Operative		Short-Term (6-12 Weeks)		Mid-Term (1 Year)		Long-Term (2 Years)		P-Value*
	(N)	Mean	(SD)	Mean	(SD)	Surgery			Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	
This study	219	68	5	10	4	b	Index		.53	(.21)	.65	(.17)	.75	(.16)	.74	(.18)	<.001
		68	5	10	4	b	VAS		56	(23)	66	(19)	73	(18)	70	(20)	<.001
Butler et al[16]	178	63	(12)	3	(1)	ALIF	Index		0.2	(.2)	0.7	(.1)	0.7	(.2)	0.8	(.1)	.02
	178	63	(12)	3	(1)	ALIF	VAS		54	20	75	(11)	76	16	78	(19)	
Sabou et al[17]	55	71	(9)	6	(3)	MPLIF	Index		.20	(.35)	na	na	.61	(.23)	na	na	na
	27	66	(6)	5	(1)	MPLIF + ALLR	Index		.19	(.30)	na	na	.59	(.34)	na	na	na
Eskilsson et al[18,19]	76	55	(16)	9	Na	PSO	Index		.21	na	na	na	.56	na	na	na	na
Molloy et al[20]	64	64	(11)	3[b]	(1)[b]	360°	Index		0.3	(.1)	0.7	(.3)	0.8	(.1)	na	na	na
		64	(11)	3[b]	(1)[b]	360°	VAS		58	(6)	78	(13)	90	(7)	na	na	na

Note: None of the cited studies, except the presented paper mentioned which level (3-L or 5-L) or the EQ-5D is used making comparisons difficult. Using the search terms "EQ-5D", "Spine", and "Deformity", PubMed.gov yielded 47 results. Eight studies were included in the table, and 39 studies were excluded. Exclusion criteria were different anatomical region (i.e., cervical spine (n = 15), hip (n = 1), thoracic spine (n = 1)), inclusion of single-level surgeries (n = 3), unrelated miscellaneous topic (i.e., validation of a disability index (n = 1), kyphoplasty (n = 1), idiopathic scoliosis (n = 4), fractures (n = 3), normative data (n = 6), quality improvement (n = 2), tumor (n = 2). When substituting "Deformity" for "Scoliosis" in the search, there were 14 additional results. Studies were excluded due to inclusion of single-level surgeries (n = 2), miscellaneous topic (i.e., kyphoplasty (n = 1), idiopathic scoliosis (n = 7), non-fusion (n = 2), sarcopenia (n = 1), foreign language (n = 1)).
Abbreviations: N (number of patients); PSF (Posterior Spinal Fusion); PI (Posterior Instrumentation); TLIF (Transforaminal Lumbar Interbody Fusion); PLIF (Posterior Lumbar Interbody Fusion); XLIF/DLIF (eXtreme Lateral Interbody Fusion/Direct Lateral Interbody Fusion); ALIF (Anterior Lumbar Interbody Fusion), AI (Anterior Instrumentation); MPLIF (multilevel posterior lumbar interbody fusion); ALLR (anterior longitudinal ligament release), PSO (pedicle subtraction osteotomy), ° (degrees).
aComparison of long-term (2 years) vs pre-operative.
bPSF; PI; TLIF; PLIF; XLIF/DLIF; ALIF; AI.

41%. Furthermore, Sharma et al[22] retrospectively analyzed 191 patients with a mean age of 64 (±11) years with ≥2 level (mean of 8 (±4)) fusion surgeries. They reported an improvement in HRQOL of at least 1 MCID (using .15) in the EQ-5D in 47%.

No study, to the best of our knowledge, has reported the residential status after multilevel spinal surgery in the elderly. However, Eastlack et al[40] undertook a retrospective review of patients treated with minimally invasive surgery for adult spinal deformity. Of 182 patients, 62% were discharged home and 37.9% were discharged to a nursing home or rehabilitation. They also found that elderly patients >70 years were 6 times more likely to be discharged to a nursing home or rehabilitation. Patients that were discharged home were less likely to have complications (40 vs 58%). Additionally, Bozic et al[41] have shown that discharge to post-acute care (e.g., rehabilitation) may account for up to 55% of the total costs. In an endeaver to decrease costs, Jubelt et al[42] have shown that >10% of patients may be discharged home without increasing readmission rates. In our series, 88.6% patients resided at home after 10 weeks and that all surviving patients were able to live at home after 24 months. Preoperatively almost all of the patients lived at home, which is substantial in this age group. Furthermore, a high portion were still recovering in rehab at 10 weeks, which suggests that the recovery from this surgery is very long, and these patients had access to substantial resources that are not available everywhere. However, at 1 and 2 years virtually all of the patients successfully made it home.

The main limitations of this study are the lack of standardized definition of spinal deformity, surgical indication and surgical techniques. However, due to the sparse literature on this topic, the current study adds helpful insights into the EQ-5D in elderly patients with multilevel surgery for spinal deformity. Another limitation is the use of the EQ-5D-3 L instead of the 5-level (5-L) version. Compared to the 5-L version, the 3-L version depicts population health as having fewer, but more severe health problems.[43] The 5-L has been shown to have increased sensitivity and precision due to superior because of distributional evenness, scale use efficiency, and face validity.[44] The anchor-based approach for MCID calculation is the most commonly used approach. It depends on the criterion scale and its levels, which makes it dependent on the number of levels with smaller differences leading to smaller MCIDs.[45] It also carries the risk of cognitive dissonance regarding decision regret. Other approaches may yield somewhat different values, but, for example, the distribution-based appraoch does not consider the actual clinical importance and depends of the variability of the investigated sample.[46] Satisfaction is a different measure as to whether a patient has improved or not. A static MCID does not take into account the baseline health-related quality of life, which affects the quantity of possible change and relevance of smallest change, which is why it needs to be interpreted with care. The external validity of this study may be limited by differences in indications and surgical treatments between other surgeons and other populations. Future studies may investigate QALYs and the cost-effectiveness as well as calculations of the substantial clinical benefit of multilevel adult spinal deformity surgery in the elderly. Lastly, the EQ-5D is a generic measure and not specific for spine pathology, which makes it prone to be influenced by other general co-morbidities. We provided baseline data for comorbidities in order to put the baseline EQ-5D values into perspective. Future studies may also record changes in these comorbidities over time. Radiological data, such as overall spinal alignment and junctional failure may also have an impact on the EQ-5D, but radiological outcomes of this study population were not the focus of this study.

Of note, we did not calculate the MCID for the EQ-VAS because the prerequisite for MCID calculation, not significant baseline values, was not met (P = .05). This means the MCID for EQ-5D VAS (MCID = 13.9 (95% CI 6.9 – 20.9)) is questionable.

Conclusion

This study provides in-depth analysis up to 24 months after ≥5 level spinal deformity surgery in elderly patients, providing a value of .22 for the MCID calculation of the EQ-5D, and a comparison to the previous sparse literature regarding similar patient cohorts. This value could be considered an indicator for sucessful deformity surgery in the elderly. Overall, the EQ-5D is an efficient questionnaire to assess patients with adult spinal deformity. The EQ-5D index significantly increased at each time point over 24 months. Only few patients had extreme problems and substantial worsening of the EQ-5D was observed in only 4.1% of patients. Patients living at home prior to surgery can expect to be able to live at home 2 years following multilevel spinal fusion for spinal deformity. In this series, the EQ-5D showed similar results to the SRS 22r, the ODI, and the NRS while allowing for QALY calculations and comparisons to other disease conditions.

ORCID iDs

Thorsten Jentzsch https://orcid.org/0000-0002-6133-3314
Stephen J. Lewis https://orcid.org/0000-0002-9173-8443
Colby Oitment https://orcid.org/0000-0003-1351-9410
Yong Qiu https://orcid.org/0000-0003-4202-6092
Kenneth M. C. Cheung https://orcid.org/0000-0001-8304-0419
Michael P. Kelly https://orcid.org/0000-0001-6221-7406

Supplemental Material

Supplemental material for this article is available online.

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