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Clinical Study

# Stratifying outcome based on the Oswestry Disability Index for operative treatment of adult spinal deformity on patients 60 years of age or older: a multicenter, multi-continental study on Prospective Evaluation of Elderly Deformity Surgery (PEEDS)

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**Abstract**

**BACKGROUND CONTEXT:** Patients with adult spinal deformity suffer from disease related disability as measured by the Oswestry Disability Index (ODI) for which surgery can result in significant improvements.

**PURPOSE:** The purpose of this study was to show the change in overall and individual components of the ODI in patients aged 60 years or older following multi-level spinal deformity surgery.

**STUDY DESIGN:** Prospective, multicenter, multi-continental, observational longitudinal cohort study

**PATIENT SAMPLE:** Patients ≥60 years undergoing primary spinal fusion surgery of ≥5 levels for coronal, sagittal or combined deformity.

**OUTCOME MEASURES:** Oswestry Disability Index (ODI)

**METHODS:** *:* Patients completed the ODI pre-operatively for baseline, then at 10 weeks, 12 months and 24 months post-operatively. ODI scores were grouped into deciles, and change was calculated with numerical score and improvement or worsening was further categorized from baseline as substantial (≥20%), marginal (≥10−<20%) or no change (within 10%).

**RESULTS:** Two-hundred nineteen patients met inclusion criteria for the study. The median number of spinal levels fused was 9 [Q1=5.0, Q3=12.0]. Two-year mean (95% CI) ODI improvement was 19.3% (16.7%; 21.9%; p<.001) for all age groups, with mean scores improved from a baseline of 46.3% (44.1%; 48.4%) to 41.1% (38.5%; 43.6%) at 10 weeks (p<.001), 28.1% (25.6%; 30.6%) at 12 months (p<.001), and 27.0% (24.4%; 29.5%) at 24 months (p<.001). At 2 years, 45.5% of patients showed 20% or greater improvement in ODI, 23.7% improved between 10% and 20%, 26.3% reported no change (defined as±10% from baseline), 4.5% of patients reported a worsening between 10% to 20%, and none reported worsening greater than 20%. 59.0% of patients were severely disabled (ODI >40%) pre-operatively, which decreased to 20.2% at 2 years. Significant improvement was observed across all 10 ODI items at 12 and 24 months. The largest improvements were seen in pain, walking, standing, sex life, social life and traveling.

**CONCLUSIONS:** In this prospective, multicenter, multi-continental study of patients 60 years or older undergoing multi-level spinal deformity surgery, almost 70% of patients reported significant improvements in ODI without taking into account surgical indications, techniques or complications. Clear data is presented demonstrating the particular change from baseline for each decile of pre-operative ODI score, for each sub-score, and for each age group. 

*Keywords:* Adult spinal deformity; Elderly; Fusion; Oswestry disability index (ODI); Outcomes; Quality of life; Sagittal malalignment; Scoliosis; Surgery; Symptomatic

## Introduction

Adult spinal deformity (ASD) is common with an estimated prevalence in the general population of 32% and up to 68% in the elderly [1−4]. The functional limitations associated with ASD may lead to a significant deterioration in quality of life [5−9]. Studies have shown adult symptomatic spinal deformity patients to have similar or worse patient reported health related quality of life (HRQoL) scores than common disease states such as arthritis, chronic pulmonary disease, congestive heart failure, diabetes and cancer [10,11]. Compared with matched controls, patients with ASD have more pain, worse self-image and greater limitations in overall function [12−15].

The Oswestry Disability Index (ODI) is a commonly used patient reported outcome score in ASD [16−21]. It is a validated score to assess back-specific symptoms or disability and distinguish between different health states. It has shown good correlation with physical functioning in patients with ASD [22]. In an effort to correlate statistical and clinically relevant changes in outcome parameters such as ODI, the minimal clinically important difference (MCID) was introduced [23,24]. Whether the MCID accurately reflects a clinically successful outcome in ASD is not well established [24−26].

Surgical deformity correction is an option for patients who have failed non-operative measures with multiple studies demonstrating lasting improvements of up to a mean of 20% in ODI [16−21]. Relative and expected changes in ODI scores are not defined for elderly patients with ASD. The aim of the current study was to assess changes in ODI scores, as well as component sub-scores, with the goal to provide practical information regarding expected outcome of multi-level spinal deformity surgeries in patients ≥60 years age.

## Materials and methods

A prospective, multicenter, multi-continental, observational longitudinal cohort study was performed of patients ≥60 years undergoing primary spinal fusion surgery of ≥5 levels for deformity. The clinicaltrails.gov identifier is: NCT02035280.

Patients were included if they were ≥60 years at the date of the surgery, underwent ≥5-level spinal fusion procedure for a coronal, sagittal or combined deformity, were capable and willing to consent, and actually signed the consent (Figure 1 representative patient). Patients were excluded if they had prior spinal surgeries except prior decompression of up to 2 levels, neurodegenerative diseases or paralysis, doubtful compliance during follow up, were institutionalized or prisoners, medically unfit, recent substance abusers, psychosocially disturbed, had an active tumor or infection, had a recent tumor or fracture of the spine, participated in other studies that could influence the results of the current study.

Demographic variables collected in this study were gender, age, height, weight, body mass index, race, work status, type of work, and American Society of Anesthesiologists grade.

Local investigators assessed and included patients for eligibility. Local surgeons performed the surgeries according to their standard of care with techniques according to their discretion. Patients were reviewed and outcome forms completed at baseline, 10 weeks, 12 months, and 24 months. Radiographs (3-foot, antero-posterior, and lateral) were acquired pre-operatively, at discharge from hospital, and after 24 months.

The outcome measure of interest for this report is the ODI, version 2.1a, one of the secondary objectives of the study. The overall ODI score was calculated by dividing the total score by the total possible score, which was then multiplied by 100 and expressed as a percentage. The "total possible score" could be either 50 (if all 10 questions were completed) or 45 (if 9 questions were completed). If more than one answer was missing, the overall score was set to missing. ODI scores were grouped into deciles. Change was calculated based on total range of ODI scale and improvement or worsening was further categorized from baseline as substantial (≥20%), marginal (≥10%−<20%) or no change (within 10%).

First, simple descriptive statistics were used to present mean and standard deviation or median and interquartile range for continuous data and absolute and relative frequency for categorical data. Afterwards, an unadjusted mixed effect linear regression model and a mixed effects linear regression model adjusted for age, bone mineral density (BMD), Charlson comorbidity score, depression (EQ-5D anxiety/depression) and pre-operative cognitive function (animal fluency test), were performed to evaluate the change of ODI over time. Subgroup analysis was performed on patients age groups by 5 years increments. The study sample size calculation was based on mean improvement of 0.5 points in SRS-22r and suggested that 225 patients would be needed. Significance was defined as $p<.05$. All statistical analyses were performed using SAS (version 9.4, SAS Institute Inc., Cary, NC, USA).

## Results

Of 255 patients enrolled, 219 patients met inclusion and none of the exclusion criteria for the study. Most patients were female (80.4%) and Caucasian (56.6%), and the mean age was 67.5 years (Table 1). The mean BMI was 26.1 kg/m$^2$ with over 50% of the patients being either overweight (29.7%) or obese (21.5%). Aggregate BMD scores demonstrated that 43% of patients had normal BMD, 45.6% of patients were osteopenic, and 11.4% were osteoporotic. Median timing of BMD (days) prior to surgery was 29.0 days [interquartile range: 8.0, 70.0]. 40.9% of patients reported no depression or anxiety, whereas 49.8% reported moderate, and 9.3% severe, depression or anxiety. The

Table 1
Demographic information of patients included in the study, n=219

| | |
|---|---|
| Baseline patient variables | |
| Female:Male, n (%) | 176 (80.4): 43(19.6) |
| Age (Y), Mean (Min, Max) | 67.5 (60, 83) |
| 6 0−64 Y, n (%) | 80 (36.5) |
| 65−69 Y, n (%) | 65 (29.7) |
| 70−74 Y, n (%) | 46 (21.0) |
| ≥75 Y, n (%) | 28 (12.8) |
| Charlson Comorbidity Index, n (%) | 219 |
| 0 | 155 (70.8) |
| 1 | 38 (17.4) |
| 2 | 19 (8.7) |
| 3 | 5 (2.3) |
| 4 | 2 (0.9) |
| BMI (Kg/m$^2$), Mean (Min/Max) | 26.1 (15.7; 49.3) |
| BMI >30, n (%) | 47 (21.5) |
| Bone Mineral Density (BMD), n (%) | 158 (100) |
| Normal bone density, n (%) | 68 (43.0) |
| Low bone density (osteopenia), n (%) | 72 (45.6) |
| Osteoporosis, n (%) | 18 (11.4) |
| Timing of BMD prior to surgery (d) | Median (Q1, Q3) |
| Total Hip | 29.0 (8.0, 70.0) |
| Region | |
| North America, n (%) | 97 (44.3) |
| Europe, n (%) | 36 (16.4) |
| Asia, n (%) | 86 (39.3) |
| Baseline Radiographic Measures | Mean (SD; min, max) |
| Thoraco-Lumbar Cobb | 31.9° (23.6°; 1.7°, 102.5°) |
| Sagittal Vertical Axis (SVA C7 − S1) | 91.9 mm (74.2; -76.3, 327.2) |
| Pelvic Tilt (PT) | 28.9° (10.2°; 8.0°, 56.6°) |
| Pelvic Incidence minus Lumbar Lordosis (PI − LL) | 28.0° (21.0°; -25.9°, 86.3°) |
| Hospital and Surgical Details | Median (Q1, Q3) |
| Length of Hospital Stay (d) | 14 (7, 32) |
| Number of Levels Fused | 9 (5, 12) |
| Duration of Surgery (minutes) | 407 (330, 476) |
| Estimated Blood Loss (cc's) | 1385 (900, 2100) |
| Surgical Approach by Patient/Stage | n (%) |
| Stage I (n=219) | |
| Anterior/Lateral | 45 (20.6) |
| Anterior/Lateral and Posterior | 6 (2.7) |
| posterior | 168 (76.7) |
| Stage II (n=53) | |
| Anterior/Lateral | 0 (0.0) |
| Anterior/Lateral and Posterior | 2 (3.8) |
| Posterior | 51 (96.2) |
| Fusion to pelvis | 178 (81.3) |

median number of spinal levels fused was 9 [interquartile range: 5, 12].

The descriptive mean ODI scores improved from a baseline of 46.3%±16.0% (mean±SD) to 41.2%±18.2% at 10 weeks, 28.2%±17.4% at 12 months, and 26.4%±17.3% at 24 months. The unadjusted mean ODI (95% CI) calculated from mixed effect model pre-operatively was 46.3% (44.1%; 48.4%), at 10 weeks post-operatively it improved to 41.1% (38.5%; 43.6%; p<.001), and further improved to 28.1% (25.6%; 30.6%; p<.001) at 12 months, and to 27.0% (24.4%; 29.5%; p<.001) at 2 years post-operatively (Table 2). The adjusted mean ODI (95% CI) pre-operatively was 46.1% (42.5%; 49.6%), at 10 weeks post-operatively it improved to 41.5% (37.9%; 45.2%) (p=.012), and further improved to 26.5% (22.8%; 30.2%; p<.001) at 12 months, and to 25.9% (22.2%; 29.6%; p<.001) at 2 years post-operatively.

The ODI scores were analyzed according to the patients' ages in 5-year increments at various time points (Table 2). All age groups had significant improvement in ODI scores at 1 and 2 years post-operatively (p<.001). However, at 10-weeks post-surgery, only patients under the age of 70 showed statistically significant benefit, whereas patients ≥75 years (ODI to 50.2%, p=.235) had worsened slightly.

At 2 years, an improvement by 20% or more in ODI compared to baseline was seen in 45.5% of patients, and 23.7% improved between 10% and 20% (Table 3). 26.3% reported no change in ODI score (defined as±10% from baseline) and 4.5% of patients reported a worsening between 10-20%. No patients deteriorated by more than 20% compared to pre-operative ODI score. According to Fairbank's original classification of ODI, pre-operatively, 5.9% of patients had minimal disability (ODI ≤20%) which improved to proportion of 15.7% at 10 weeks, 38.2% at 1 year, and to 41.1% at 2 years (Table 4) [27]. Conversely, 59.0% of patients were severely disabled (ODI >40%) pre-operatively, which decreased to proportion of 50.3% at 10 weeks, 25.3% at 1 year and 20.2% at 2 years.

A shift table of patients divided into deciles is presented in Table 5. This depicts the improvement seen based on the baseline ODI. For example, of the 41 patients with a pre-operative ODI between 51% to 60%, 7 patients (17%) improved 5 deciles (range; 41%−60% improvement), 5 patients (12%) improved 4 deciles (range; 31%−50% improvement), 5 patients (12%) improved 3 deciles (range; 21%−40% improvement), 10 patients (24%) improved 2 deciles (range; 11%−30% improvement), and 8 patients (20%) improved 1 decile (range; 1%−20% improvement), while 4 patients (10%) stayed in the same decile and 2 patients (5%) worsened 1 decile. In contrast, of the 17 patients with baseline ODI between 21%−30%, 35% improved 2 deciles, 35% improved 1 decile, 6% remained in the same decile, 6% worsened 1 decile, and 18% worsened 2 deciles.

Overall change of ODI based on pre-operative score is depicted in Table 6. The chance of improving at least 1 decile in the ODI at 24 months was greatest in the patients with the worse baseline scores. Patients starting with ODI between 71% to 80% (n=5) had a 100% chance of improving of at least 1 decile, whereas, patients with baseline ODI between 11% to 20% (n=8) had only a 62.5% chance of improving of at least 1 decile.

Significant improvement was observed across all ten ODI items at 12 and 24 months (Personal care: p<.05, Sex Life: p<.05 at 1 year; all other comparisons: p<.001, Table 7). Improvements seen at 1 year were generally maintained at 2 years. However, results at 10 weeks were mixed,

Table 2
Unadjusted baseline ODI and follow-up scores displayed as mean (N; 95% CI) by age category at pre-operative and 10 wk, 12 mo, and 24 mo post-operative time points. Comparisons at each post-operative time point are made vs. pre-operative mean ODI

| Age group | Pre-op | 10 wk Post-op | 12 mo Post-op | 24 mo Post-op |
|---|---|---|---|---|
| All Patients | 46.3 (205; 44.1−48.4) | 41.1 (191; 38.5−43.6)** | 28.1 (178; 25.6−30.6)** | 27.0 (168; 24.4−29.5)** |
| Age 60−64 | 46.8 (74; 43.2−50.5) | 38.0 (69; 33.8−42.2)** | 26.7 (64; 22.5−31.0)** | 25.4 (55; 21.0−29.8)** |
| Age 65−69 | 46.3 (63; 42.4−50.3) | 39.8 (56; 35.2−44.5)* | 30.1 (52; 25.5−34.7)** | 27.8 (53; 23.2−32.4)** |
| Age 70−74 | 45.9 (43; 41.1−50.7) | 42.6 (42; 37.2−48.0) | 28.5 (41; 23.2−33.9)** | 26.5 (40; 21.1−31.9)** |
| Age ≥75 | 45.2 (25; 38.9−51.5) | 50.2 (24; 43.1−57.3) | 26.1 (21; 18.9−33.4)** | 30.8 (20; 23.5−38.2)** |

* p<.05,
** p<.001

Table 3
Total change in ODI at 2-y

| | Improvement | | No change | Worsening | |
|---|---|---|---|---|---|
| % Change in ODI | ≥20% | ≥10% < 20% | Within 10% | ≥10% < 20% | ≥20% |
| N (%) | 71 (45.5) | 37 (23.7) | 41 (26.3) | 7 (4.5) | 0 (0.0) |

Change in ODI comparing pre-operative to 24 mo scores.

Table 4
ODI over the course of follow-up. The number of patients is displayed within each quintile of unadjusted ODI scores according to Fairbank's classification at pre-operative and 10 wk, 12 mo, and 24 mo post-operative time points

| Oswestry disability index (%) | Pre-op N=205 | 10 wk N=191 | 12 mo N=178 | 24 mo N=168 |
|---|---|---|---|---|
| 0%−20% N (%) | 12 (5.9) | 30 (15.7) | 68 (38.2) | 69 (41.1) |
| 21%−40% N (%) | 72 (35.1) | 65 (34.0) | 65 (36.5) | 65 (38.7) |
| 41%−60% N (%) | 84 (41.0) | 67 (35.1) | 38 (21.3) | 29 (17.3) |
| 61%−80% N (%) | 34 (16.6) | 27 (14.1) | 7 (3.9) | 5 (3.0) |
| 81%−100% N (%) | 3 (1.5) | 2 (1.0) | 0 (0.0) | 0 (0.0) |

with significant worsening seen in lifting and personal care domains (both p<.001), and significant improvements seen in sleeping (p<.05), walking (p<.05), pain (p<.001), and standing (p<.001).

## Discussion

This multicenter, multi-continental, prospective study of patients ≥60 years undergoing multi-level spinal fusion surgery, demonstrated significant overall ODI improvement of 19.3%, with significant improvements in all subdomains. Close to 70% of patients enjoyed improvement in overall ODI from baseline to 1 and 2 years' post-surgery. ODI has shown to have good internal validity when distinguishing between the severity of functional disability and is a valid tool in the adult spinal deformity population [22,27]. This study had one of the highest disability levels at baseline reported in the literature [17,28−30]. Greatest improvement was seen in patients with higher ODI scores at baseline. Furthermore, clear data is presented demonstrating the particular change from baseline for each decile of pre-operative ODI score, for each sub-score, and for each age group. In this manner, patients can be educated pre-operatively on the expected outcome based on their particular baseline disability.

Whereas the majority of patients showed major decreases in their ODI scores, a certain recovery period was needed. Most of the improvement in ODI occurred within the first year and was maintained at 2 years post-operatively. At 10 weeks, the majority of patients had scores described in the moderate (ODI 21%−40%) to severe (ODI 41%−60%) disability categories, which would be expected in the recovery period after major spinal fusion surgeries [31]. This change was greatest in the ≥75-year-old subgroup. At 2 years, younger age groups showed a greater improvement in ODI, with a mean improvement of 21.4% in ages 60 to 64, compared to 14.4% in the patients ≥75 years of age.

Despite the good results seen in this study, the mean ODI score of 27.0% at 2 years represents moderate disability. This score is well above the normative mean, which is approximately 10.2%, equivalent to spondylolisthesis (26.6%) and primary back pain (27.0%), and well below chronic back pain (43.3%), sciatica (44.7%), and metastases (48.0%) [31]. A study of 1200 Japanese reported a normative mean ODI of 8.73% in respondents without back pain,

Table 5
Shift table of pre-operative and 2-y follow-up ODI scores divided into deciles

| Pre-op Oswestry Disability Index | | Oswestry Disability Index (ODI) at 24 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Score | N (%) | 0%-10% | 11%-20% | 21%-30% | 31%-40% | 41%-50% | 51%-60% | 61%-70% | 71%-80% | 81%-90% | 91%-100% |
| 0%-10% | 2 (1.3) | 1 (50.0) | 0 (0.0) | 1 (50.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| 11%-20% | 8 (5.1) | 5 (62.5) | 2 (25.0) | 1 (12.5) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| 21%-30% | 17 (10.9) | 6 (35.3) | 6 (35.3) | 1 (5.9) | 1 (5.9) | 3 (17.6) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| 31%-40% | 38 (24.4) | 11 (28.9) | 8 (21.1) | 12 (31.6) | 5 (13.2) | 2 (5.3) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| 41%-50% | 28 (17.9) | 5 (17.9) | 5 (17.9) | 5 (17.9) | 8 (28.6) | 2 (7.1) | 3 (10.7) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| 51%-60% | 41 (26.3) | 7 (17.1) | 5 (12.2) | 5 (12.2) | 10 (24.4) | 8 (19.5) | 4 (9.8) | 2 (4.9) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| 61%-70% | 17 (10.9) | 1 (5.9) | 2 (11.8) | 3 (17.9) | 4 (23.5) | 4 (23.5) | 2 (11.8) | 0 (0.0) | 1 (5.9) | 0 (0.0) | 0 (0.0) |
| 71%-80% | 5 (3.2) | 0 (0.0) | 0 (0.0) | 1 (20.0) | 2 (40.0) | 0 (0.0) | 0 (0.0) | 2 (40.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| 81%-90% | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| 91%-100% | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Total | 156 (100.0) | 36 (23.1) | 28 (17.9) | 29 (18.6) | 30 (19.2) | 19 (12.2) | 9 (5.8) | 4 (2.6) | 1 (0.6) | 0 (0.0) | 0 (0.0) |

Scores in black represent patients that stayed in their ODI decile, scores in light gray indicate patients that showed improvement by decile, and scores in dark gray indicate patients that showed worsening by decile.

22.07% in people with back pain and disability, and displayed a trend of increasing ODI with increased age [32]. Mannion et al. described the PASS (patient acceptable symptom state) score, defining an ODI threshold score of ≤29 for patients ≥50 years of age undergoing spinal deformity surgery [33]. Using this as the benchmark, 60% of our cohort reached this threshold at 2-years follow-up compared to 17% at baseline, despite our patients being at least 10 years older on average. While 41% of the patients in this series had 2-year follow-up ODI scores ≤20%, with more than half of these at the normative mean or better, 21% of patients remained severely disabled (ODI ≥41%). This suggests that there likely is a certain ceiling effect to the overall benefits of a multi-level spinal fusion, or that other demographic, comorbidities, surgical, or adverse events, factor in to the score.

This study reported the percentage change from baseline at time points 10 weeks, 1 year and 2 years, and grouped patients into deciles comparing their baseline to 2-year follow-up. By doing this, we were able to create an easily interpretable visual representation of patients who improved (≥1 decile group), did not change (remained in same decile group) or worsened (≥1 decile group). Almost 70% of patients improved at least one decile group, with 45% of patients improving by a minimum of two deciles. Patients with greater baseline ODI showed greater improvement in ODI at 2 years, with 95% of patients (21 of 22 patients) with baseline ODI of 61% to 80% improving a minimum of 1 decile group, to a maximum of six deciles, at 2 years. At 2 years, severe disability (ODI ≥41%), was still present in 21% of patients, of which 48.5% reported a ≥1 decile improvement, 18.2% were unchanged and 33.3% worsened with a ≥1 decile decline of their ODI compared to their pre-operative status.

When analyzing the individual components of the ODI, this study showed significant improvements in all ODI items at 1- and 2-years post-surgery. Yoshida et al. showed similar trends in the individual components in their study and calculated individual MCID values for each subscore [24]. In our study, 6 of 10 measures showed a mean improvement of ≥1 point (pain, walking, standing, sex life, social life, travel) while four improved <1 point (personal care, lifting, sitting, sleeping). While we did not calculate MCID values for individual ODI components, the four remaining components improved >0.5 points, which is similar or greater than those reported by Yoshida et al.

MCID is the most commonly used method for assessing a clinically important change in patient-reported outcome measures. In the adult spinal deformity population, agreement on an MCID value has been difficult as there are not only different methods of calculating MCID, but there is also discrepancy in what constitutes a clinically important change based upon the severity of the deformity [24–26]. This study chose to report changes in ODI as a percentile change from baseline and displayed the data in deciles. One of the limitations of this method is it does not represent the absolute percentage change in ODI, but rather categorically groups individuals into deciles to then account for the

Table 6
Summary of shift table divided into deciles

| Preoperative ODI | | Change in ODI decile at 24 mo Post-op | | |
|---|---|---|---|---|
| Range | N (%) | % Improved | % Unchanged | % Worse |
| 0%–10% | 2 (1.3) | 0% | 50% | 50% |
| 11%–20% | 8 (5.1) | 62.5% | 25% | 12.5% |
| 21%–30% | 17 (10.9) | 70.6% | 5.9% | 23.5% |
| 31%–40% | 38 (24.4) | 81.6% | 13.2% | 5.3% |
| 41%–50% | 28 (17.9) | 82.1% | 7.1% | 10.7% |
| 51%–60% | 41 (26.3) | 85.4% | 9.8% | 4.9% |
| 61%–70% | 17 (10.9) | 94.1% | 0% | 5.9% |
| 71%–80% | 5 (3.2) | 100% | 0% | 0% |
| 81%–90% | 0 (0) | N/A | N/A | N/A |
| 91%–100% | 0 (0) | N/A | N/A | N/A |
| Total | 156 (100) | 81.4% | 9.6% | 9.0% |

Percentage of patients who shifted deciles from baseline to 2-y without consideration for magnitude of individual change.

magnitude of change. In a recent study by Yoshida et al, they reported an overall improvement in ODI at 11% as reaching MCID [24]. In our study, change in deciles based on the pre-operative ODI is clearly illustrated, so that patients can be provided with a clear picture on their particular chance of an expected outcome. A patient starting with a baseline ODI of 59% that improves by MCID (11%), while being considered a statistical success, would still remain with significant disability (ODI 48%) at 2 years. With the more granular data provided in this study, we can now state that this patient at 2 years, has a close to 30% chance of having minimal disability (ODI ≤20%) and a further 35% chance of moderate disability (ODI ≤40%), close to 20% chance of minor improvement, and a 15% chance of being the same or slightly worse. This is valuable information that can help in an informed consent.

Limitations of this study include the lack of standardization in surgical indications, techniques, and peri-operative management. Further, the results did not account for complications and the effect they have on ODI. Karabulut et al. reported a significant difference in ODI improvement between their complication positive and negative groups [28]. However, we feel the results provided offer significant information to physicians and patients who are not aware pre-operatively which adverse events will occur in which patient. As part of the study exclusion criteria, patients who were deemed medically unfit or with psychosocial disturbance were not enrolled at the discretion of the local investigator. This may have introduced selection bias as this cohort of patients were relatively healthy measured by the Charlson comorbidity index as only 7 (3.2%) patients scored ≥3 or excluded patients with major mental illness. Another limitation of this study were patients lost to follow-up (n=32) and patients with missing or incomplete ODI data (n=31). As an example, three patients who were included in Table 4 with baseline ODI between 81-100% did not complete follow-up as per the study protocol, thus were not included in the complete case approach data analysis (Tables 3, 5 and 6). In addition, calculation of ODI was based upon patients answering at least 9 of 10 questions in this study. ODI version 2.1a asks a question regarding sex life which had a high non-response rate in survey at all time points (baseline 59.2%, 10 weeks 68.9%, 1 year 67.2%, 2 years 61.6%). The next highest non-response rate for any question and any time point was 4.8% (social life, 10 weeks). There also appears to be a ceiling effect in this study, similar to those seen in other studies of this patient population. Based upon ODI score, moderate disability still exists post-surgery, even with a favorable outcome, which, may be in part, attributed to the non-specific nature of the ODI. This study chose to report ODI in deciles, different from the quintiles described in the original study by Fairbank, to provide more granular data [31]. Further research into the factors that lead to the subset of patients that report residual severe disability would be beneficial.

This is the first prospective, multicenter, multi-continental study to show significant improvements in overall and individual components of the ODI in patients 60 years and older following multi-level spinal deformity surgery with

Table 7
Unadjusted mean ODI items at pre-operative and 10 wk, 12 mo, and 24 mo post-operative time points using Cochrane-Armitage trend test

| ODI items | Pre-op | 10 wkPost-op | 12-mo Post-op | 24 Mo Post-op | Change Baseline to 2 y |
|---|---|---|---|---|---|
| Pain intensity | 2.5 (1.3) | 1.5 (0.9)** | 1.1 (0.7)** | 1.2 (1.1)** | -1.2 (1.3) |
| Personal care | 1.3 (1.3) | 1.8 (2.0)** | 0.9 (1.5)* | 0.7 (1.2)** | -0.5 (1.3) |
| Lifting | 3.0 (1.4) | 3.5 (1.3)** | 2.5 (2.0)** | 2.4 (2.2)** | -0.6 (1.6) |
| Walking | 2.4 (1.5) | 2.0 (2.2)* | 1.4 (1.7)** | 1.4 (1.9)** | -1.0 (1.5) |
| Sitting | 1.7 (1.3) | 1.9 (1.2) | 1.3 (1.2)** | 1.2 (0.7)** | -0.5 (1.1) |
| Standing | 3.1 (1.3) | 2.3 (2.0)** | 1.8 (2.0)** | 1.7 (2.0)** | -1.5 (1.5) |
| Sleeping | 1.3 (1.3) | 1.0 (1.0)* | 1.7 (2.0)** | 0.8 (0.8)** | -0.5 (1.2) |
| Sex life | 2.8 (3.1) | 2.5 (3.7) | 1.8 (3.6)* | 1.5 (3.7)** | -1.1 (1.6) |
| Social life | 2.5 (1.5) | 2.4 (2.0) | 1.5 (1.8)** | 1.3 (1.9)** | -1.2 (1.5) |
| Travelling | 2.4 (2.2) | 2.1 (2.6) | 1.3 (1.5)** | 1.0 (1.4)** | -1.1 (1.4) |

* p<.05,
** p<.001

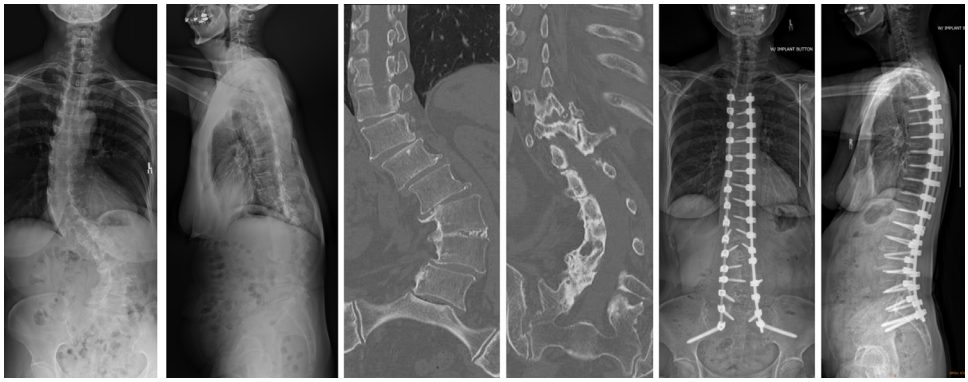

Figure 1. 63-year-old female with thoracolumbar coronal and sagittal deformity, presented with back dominant pain with a baseline ODI of 28.9% (Figures A and B). The patient had anterior column auto fusion of L3 and L4, with posterior column auto fusion of L3 − 5 (Figures C and D). Following correction of her deformity with a T4 − pelvis with multiple posterior column osteotomies (Figures E and F), ODI increased to 44.5% at 10 wk, before improving to 15.6% at 1 y and 6.7% at 2-y follow-up. Greatest ODI improvements were seen in pain (3−0), walking (1−0) and standing (2−0) domains.

mean (95% CI) ODI improvement of 19.3% (16.7%; 21.9%; p<.001). At 2 years, almost 70% of patients reported significant improvements in ODI, with 60% achieving the PASS (patient acceptable symptom state) threshold, without taking into account surgical indications, techniques or complications. Clear data is presented demonstrating the particular change from baseline for each decile of pre-operative ODI score, for each sub-score, and for each age group. This information is important and generalizable for spinal surgeons when counselling patients on expected outcomes and limitations of adult spinal deformity surgery.

Figure 1.

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## Declarations of Competing Interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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