

## Does the severity of pain correlate with severity of functional disability? Factors influencing 'patient reported outcome measures' in spinal patients

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**Abstract – Aims:** To assess correlation between the Visual Analogue Scale (VAS) pain score and the Oswestry Disability Index (ODI) and which patient factors can influence patient-reported outcome measures (PROMs). This study also aims to assess the response to the sexual function question of the ODI.

**Methods:** Retrospective analysis of 200 consecutive patients undergoing a range of different lumbar spinal procedures between July 2012 and September 2015 was performed. Subgroup analysis was also performed on the 122 patients who underwent microdiscectomy and/or decompression procedures only. Data from notes and clinical letters from the patient's first clinic appointment were collected. In addition to these outcome measures, data were also extracted regarding patients' gender, age, smoking status, alcohol use, employment and mental health status.

**Results:** Significant correlation was found between VAS pain score and ODI ( $p = 0.002$ ) and between VAS pain score and question 1 of ODI ( $p = 0.0001$ ). A lower ODI score was reported at time of surgery by those in employment compared to those who are unemployed ( $p = 0.008$ ). In addition to this, a lower ODI score was reported in those who are self-employed compared to those in employment ( $p = 0.048$ ) in both cohorts. A significantly higher mean ODI score was shown within the subgroup analysis for current smokers ( $p = 0.02$ ). None of the other patient factors that were analysed were found to affect PROMs. 65% of patients answered the sexual function question of the ODI.

**Conclusions:** Significant correlation was demonstrated between VAS pain score and ODI. Those who are in employment are far more likely to report a lower ODI score than those who are unemployed at the time of surgery. Self-employed patients were found to have reported a significantly lower ODI score than those who are in employment. Smoking cessation should be encouraged as those who are current smokers may be more likely to report a higher ODI. As 65% of patients decided to answer the sexual function question of the ODI, this supports its further use.

**Key words:** Patient reported outcome measures, PROMs, Oswestry disability index, VAS pain score, Lumbar spinal surgery.

### Background

Back pain has been defined as the leading cause of disability in the UK [1], affecting 15% of adults and the impact that this can have on a patient's quality of life (QOL) can be severe. Physicians are now encouraged to monitor the impact of a patient's condition on their everyday living both before and after surgery [3].

The Visual Analogue Scale (VAS) and the Oswestry Disability Index (ODI) are two commonly used systems to measure patient-reported outcome measures (PROMs) in

spinal patients. The VAS is a unidimensional measure of pain intensity that is widely used for a range of conditions. The ODI, on the other hand, is a condition-specific measure for the assessment of outcomes in spinal pathologies. This tool, developed by Fairbank [4] in 1980, has been extensively tested by various authors for its applicability and reliability [5]. They concluded that it is an effective instrument for the disability assessment of lumbar spine pathology as it addresses both pain and function (Figure 1).

A range of different patient factors have been shown to also impact these outcome measures. A large proportion of patients who are off work due to their back pain have been

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# **oswestry low back pain questionnaire**

name ..... address ..... date .....

date of birth ..... age..... .....

occupation .....

how long have you had back pain? ..... years ..... months ..... weeks

how long have you had leg pain? ..... years ..... months ..... weeks

*please read:*

this questionnaire has been designed to give the doctor information as to how your back pain has affected your ability to manage in everyday life – please answer every section, & mark in each one

only the *one box* which applies to you. we realise you may consider that 2 statements in any 1 section relate to you, but please *just mark the box which most closely describes your problem*

## **section 1 - pain intensity**

- I can tolerate the pain I have without having to use pain killers
- the pain is bad but I manage without taking pain killers
- pain killers give complete relief from pain
- pain killers give moderate relief from pain
- pain killers give very little relief from pain
- pain killers have no effect on the pain and I do not use them

## **section 2 - personal care (washing, dressing, etc)**

- I can look after myself normally without causing extra pain
- I can look after myself normally but it causes extra pain
- it is painful to look after myself and I am slow and careful
- I need some help but manage most of my personal care
- I need help every day in most aspects of self care
- I do not get dressed, wash with difficulty and stay in bed

## **section 3 - lifting**

- I can lift heavy weights without extra pain
- I can lift heavy weights but it gives extra pain
- pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, eg on a table
- pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned
- I can lift only very light weights
- I cannot lift or carry anything at all

## **section 4 - walking**

- pain does not prevent me walking any distance
- pain prevents me walking more than 1 mile
- pain prevents me walking more than 1/2 mile
- pain prevents me walking more than 1/4 mile
- I can only walk using a stick or crutches
- I am in bed most of the time and have to crawl to the toilet

## **section 5 - sitting**

- I can sit in any chair as long as I like
- I can only sit in my favourite chair as long as I like
- pain prevents me from sitting more than 1 hour
- pain prevents me from sitting more than 1/2 hour
- pain prevents me from sitting more than 10 minutes
- pain prevents me from sitting at all

## **comments**

## **section 6 - standing**

- I can stand as long as I want without extra pain
- I can stand as long as I want but it gives me extra pain
- pain prevents me from standing for more than 1 hour
- pain prevents me from standing for more than 1/2 hour
- pain prevents me from standing for more than 10 minutes
- pain prevents me from standing at all

## **section 7 - sleeping**

- pain does not prevent me from sleeping well
- I can sleep well only by using tablets
- even when I take tablets I have less than six hours sleep
- even when I take tablets I have less than four hours sleep
- even when I take tablets I have less than two hours sleep
- pain prevents me from sleeping at all

## **section 8 - sex life**

- my sex life is normal and causes no extra pain
- my sex life is normal but causes some extra pain
- my sex life is nearly normal but is very painful
- my sex life is severely restricted by pain
- my sex life is nearly absent because of pain
- pain prevents any sex life at all

## **section 9 - social life**

- my social life is normal and gives me no extra pain
- my social life is normal but increases the degree of pain
- pain has no significant effect on my social life apart from limiting my more energetic interests, eg dancing etc
- pain has restricted social life and I do not go out as often
- pain has restricted my social life to my home
- I have no social life because of pain

## **section 10 - travelling**

- I can travel anywhere without extra pain
- I can travel anywhere but it gives me extra pain
- pain is bad but I manage journeys over two hours
- pain restricts me to journeys of less than one hour
- pain restricts me to short necessary journeys of less than 1/2 hour
- pain prevents me from travelling except to the doctor or hospital

from: Fairbank J C T, Couper J, Davies J B & O'Brien J P  
*Physiotherapy* 1980; 66: 271-73

Figure 1. Summary of the ODI.

found to remain off work even after surgery [6], so research is required to assess how the highest level of HRQoL can be achieved. The first step for this process will be to assess

which patient groups to target this at, and hence why this study will aim to assess which patient factors can influence PROMs.

## Aims

The aims of this study are to assess correlation between the VAS pain score and the ODI and which patient factors can influence PROMs. This study will also assess the response to the sexual function question of the ODI.

## Methods

### Patients

The setting for this study was a multicultural tertiary neurosurgery centre in a developed western country. Retrospective analysis was undertaken on 200 consecutive patients who underwent a range of different lumbar spinal procedures between July 2012 and September 2015. This patient group was defined as cohort 1. Subgroup analysis for patient factors was also performed on the 122 patients within this cohort who underwent microdiscectomy and/or decompression procedures and this patient group was defined as cohort 2. Inclusion criteria were that the patients were all seen within this time period and were all under the care of and operated on by the same surgeon to ensure consistency of data. All patients with incomplete information regarding their VAS pain score or ODI score were excluded from this analysis and the subsequent data interpretation. When statistical analysis was required, patients were divided into VAS groups based on their level of pain: mild (<4), moderate (5–7) and severe (>8).

### Treatment

All of the patients in the main cohort group underwent a range of different lumbar spinal procedures including microdiscectomy, decompression, fusion, nerve root injection and laminectomy. The patients in the subgroup only underwent microdiscectomy and decompression procedures. These operations were performed by the same surgeon who saw them at their first clinic consultation.

### Outcome measure and baseline data

Data were collected using the notes and clinical letters from the patient's first clinic appointment. PROMs were all taken at this appointment including ODI and VAS pain score. The ODI index, which includes 10 items, is a commonly used outcome measure for reporting how a patient's back or leg pain is affecting their ability to manage daily living. Recent literature has demonstrated that it shows good psychometric properties and is an effective tool for reporting functional outcome following spinal surgery [7]. Each of the 10 items on the index is scored from 0 to 5, with the maximum possible score being 50 [8]. To achieve a percentage, as is reported in this study, the total score must be multiplied by 2. Patients were not grouped on the basis of their ODI score. The VAS pain scale is one of the most commonly used methods to record patient pain [10]. Patients were asked to report their

**Table 1.** Divisions within each patient factor group.

Patient Factor	Groups Divisions		
Age	<40	40-60	>60
Smoking Status	Current Smoker	Ex-Smoker	Never Smoked
Alcohol Use	Heavy (>14 units per week)	Mild (<14 units per week)	None
Employment	Employed	Self Employed	Retired Unemployed
Mental Health Status	Known mental health condition		No known mental health condition

current level of back and leg pain on a scale of 0–10, representing a scale of pain from none at all to the most excruciating pain possible.

In addition to these outcome measures, data were also extracted regarding patients' gender, age, smoking status, alcohol use, employment and mental health status. This was also obtained from the notes and clinical letters from patients' first clinic appointment.

### Statistical analysis

Statistical analysis was performed using the SPSS statistical software [10]. VAS pain score and ODI score were analysed using a two-sample (unpaired) *t*-test to analyse the difference between the means. Mean ODI score was compared with mean VAS pain score for each of the mild, moderate and severe groups.

When considering the other patient factors, the same statistical analysis software and method was used. The divisions within each of these groups are demonstrated in Table 1. A *p* value for all data of <0.05 was considered significant.

## Results – main cohort

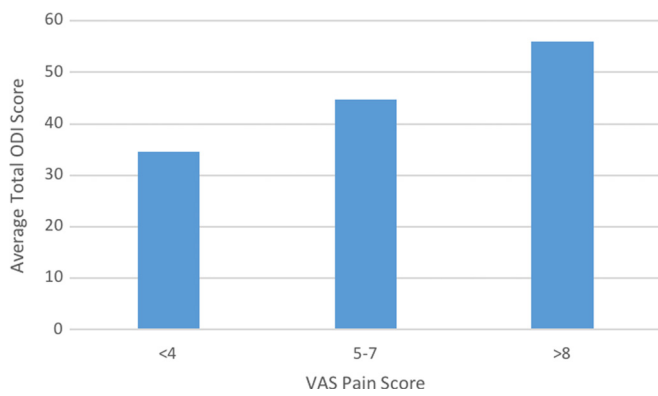
### Correlation between VAS pain score and ODI

Results from all 200 patients were obtained. Significant correlation was found in all groups of patients. When comparing the mild VAS pain score group to the moderate group, a difference in mean overall ODI score of 10.2 was found ( $p=0.002$  (95% CI 3.83–16.58)). A similar difference was also seen when comparing the moderate group to the severe group, when an average ODI score difference of 11.19 was found ( $p\leq 0.0001$  (95% CI 6.28–16.10)) (Figure 2).

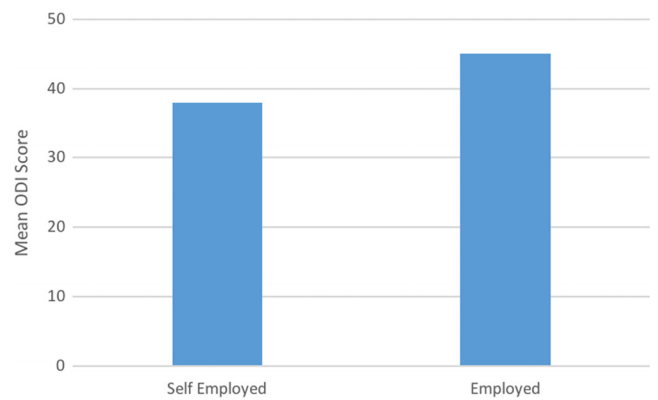
Statistical significance was also found when comparing VAS pain score to question 1 of the ODI, that being the question focusing on the severity of current pain levels. Comparing the moderate group to the severe group, there was an average question 1 VAS pain score difference of 0.65 ( $p=0.0001$  (95% CI 0.33–0.96)) (Figure 3).

### Impact of patient factors on outcome measures

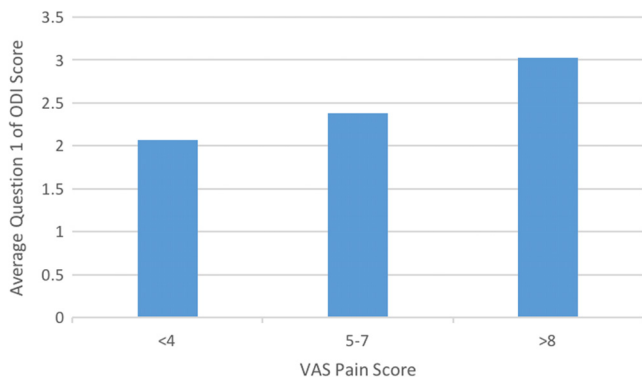
Employment status was found to have the most significant impact on PROMs. A significantly lower



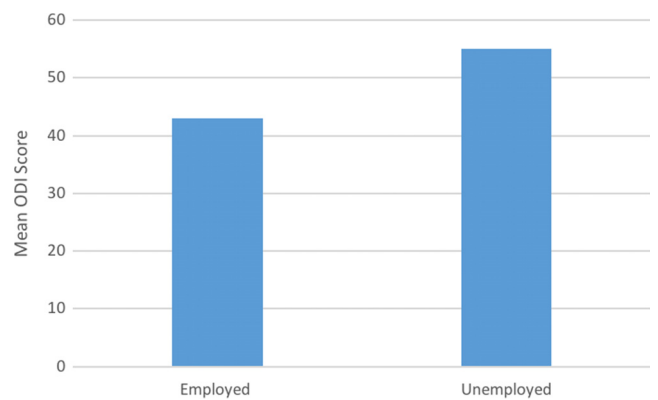
**Figure 2.** Graph comparing VAS pain score with average total ODI score.



**Figure 4.** Graphical representation of the mean ODI score of those that are self-employed compared to those in employment.



**Figure 3.** Graph comparing VAS pain score with average question 1 score of the ODI.



**Figure 5.** Graphical representation of the mean ODI score of those that are employed compared to those that are unemployed.

mean ODI score was found when comparing those who are self-employed ( $n = 22$ ) to those who are in public or private sector employment ( $n = 46$ ). An ODI difference of 6.8 ( $p = 0.0479$  (95% CI 0.06–13.57)) was observed (Figure 4).

Furthermore, more significant results were seen when comparing those who are currently in any form of employment ( $n = 68$ ) to those who are unemployed ( $n = 29$ ). An ODI difference of 12.2 ( $p = 0.0078$  (95% CI 3.24–20.76)) was found, with those who are in employment reporting a lower ODI score (Figure 5).

When considering the other patient factors that were analysed: age, gender, smoking status and alcohol use, no other statistically significant differences were found within these groups. The results that were obtained are shown in Table 2.

**Response to question 8 (sexual function) of the ODI**

Of the 200 patients, 130 patients (65%) chose to answer question 8, regarding sexual function, of the ODI while 70 patients (35%) chose not to. In the patients who declined to answer this question, this had no bearing on their responses to the rest of the questions as a completion rate of 100% was achieved for the questionnaire (Figure 6).

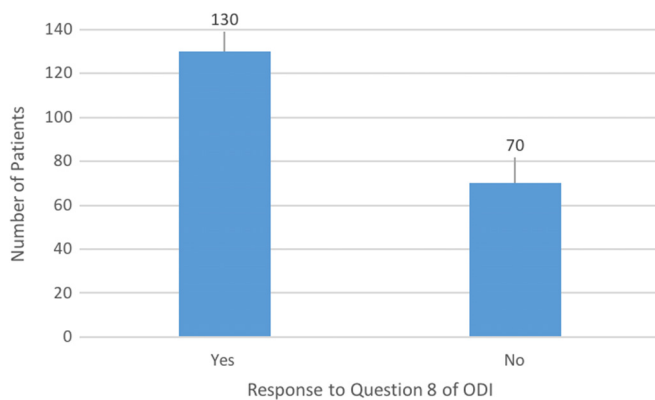
**Table 2.** Summary of the results of the impact of the other measured patient factors on ODI within Cohort 1.

Patient Factor Parameter	Cohorts Analysed			Was Statistical Significance Established When Compared to Total ODI Score?
	<40 (n=52)	40-60 (n=61)	>60 (n=87)	
Age	<40 (n=52)	40-60 (n=61)	>60 (n=87)	NO (p=0.311)
Gender	Male (n=93)		Female (n=107)	NO (p=0.190)
Alcohol Usage	Heavy (n=29)	Mild (n=134)	None (n=37)	NO (p=0.262)
Smoking Status	Current Smoker (n=51)	Ex Smoker (n=24)	Never Smoked (n=125)	NO (p=0.350)

**Results – subgroup analysis**

**Impact of patient factors on outcome measures**

The results from the subgroup analysis of cohort 2 also demonstrated a significantly lower mean ODI score in those who are self-employed ( $n = 15$ ) compared to those who are in any public or private sector employment ( $n = 31$ ). There was a mean ODI score difference of 7.2 ( $p = 0.032$  (95% CI 0.91–13.32)) with those who are self-employed reporting the lower scores.



**Figure 6.** Graphical representation of the response to question 8 of the ODI.

Furthermore, similarly significant results were also found when comparing those who are currently in any form of employment, including self-employed, ( $n = 46$ ) to those who are unemployed ( $n = 29$ ). A mean ODI score difference of 11.2 ( $p = 0.0092$  (95% CI 2.98–18.76)) was demonstrated.

Interestingly, within this subgroup analysis, a significant difference was found when comparing those who currently smoke with those who have never smoked. A mean ODI score difference of 7.9 ( $p = 0.02$  (95% CI 1.12–14.76)) was shown with those who have never smoked demonstrating the lower mean ODI score.

As with cohort 1, no statistically significant differences were found when analyzing age, gender and alcohol use.

## Discussion

The significant correlation between the VAS pain score and the ODI demonstrated in this study supports their simultaneous use to enable both corroboration of score and further understanding of different sources of pain. The main conclusion from a recent meta-analysis found ‘little correlation between the VAS pain score and ODI’, so extensive further research was recommended in order to assess the correlation between these two measures further [11]. The results from this study aim to do this by clearly demonstrating the positive correlation between these two measures, thus further supporting the need for further research into this topic.

Due to the high percentage of those with back pain not returning to work after surgery, further consideration into the reasons behind this is essential. Recent studies have highlighted the need for research to occur into the impact of employment status on PROMs [13], and this was in keeping with this studies finding of employment status being the only patient factor to do this. Those in employment were shown to be more likely to report a lower ODI score than those who are currently unemployed. While assumptions that those who are unemployed may be somewhat exaggerating, the degree of

their disability cannot be made from this study alone, this must be considered. Along with this, findings from this study that those who are self-employed were more likely to report a lower ODI score than those in employment is in line with recent literature. This demonstrated that those who are self-employed are likely to be more determined to return to work quicker than those who are employed by a company due to their lack of entitled sick pay [14]. This is an important consideration when assessing the reasons why some patients fail to return to work after surgery.

The subgroup analysis of the microdiscectomy and decompression patient cohort demonstrated a significantly greater mean ODI score in those that currently smoke. Recent literature has demonstrated increased complication rates in smokers [15], so this adds further evidence to the importance of counselling smokers with regard to cessation prior to their procedure as this could also impact the long-term outcomes after their operation.

Significant attention has also been given to question 8 of the ODI in recent research, providing conflicting information. Response rates of 18% [16], 36% [17] and 52% [18] have been found for this question on three recent large studies. The response rate of 65% found in this study is higher than the other pieces of literature; this, however, still does show that there is a degree of apprehension from patients regarding the completion of this question.

## Limitations

The greatest limitation within this study is the inclusion of a range of different lumbar spinal procedures in the main cohort of patients which ranged from nerve root blocks to spinal fusions. As a result of this, the subgroup analysis was performed on the biggest patient population that shared the same operative procedure. The patient cohort size for this study was moderate but was strengthened due to the single surgeon experience that was involved in the analysis in order to maintain consistency of data.

## Conclusion

This study has demonstrated significant correlation between the VAS pain score and the ODI. This serves to support their simultaneous use in clinical practice. In addition to this, employment status and smoking status have been shown to have a significant impact on PROMs. This should be taken into consideration in clinical practice as additional measures could be put in place in order to try and encourage eventual return to employment and smoking cessation. A response rate of the sexual function question of the ODI of 65% is considered adequate and this encourages its continued use.

## Conflict of interest

The authors declare that they have no conflict of interest.

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