Jeremy Fairbank MD FRCS
Professor of Spine Surgery
3rd Generation Orthopaedic Surgeon

- Sir Thomas Fairbank FRCS
  - Gt Ormond Street Children’s Hospital
  - Kings College Hospital, London
- John Fairbank FRCS
  - Addenbrookes Hospital, Cambridge
2 year Fellowship at Oswestry

• Dr John O’Brien
• Publications include Oswestry Disability Index
  – Most cited publication
  – ODI now adopted by ICHOM as a recommended PROM
Consultant Orthopaedic and Spine Surgeon in UK

• London, Birmingham, and since 1989...
  – Oxford

• Set up and principal Investigator of MRC Spine Stabilisation Trial
  – ODI primary outcome measure
  – Largest trial comparing surgery with intensive rehabilitation as treatment for chronic low back pain
  – Now completed 11 year follow up
OSWESTRY DISABILITY INDEX

Jeremy Fairbank
Professor of Spine Surgery
Oxford, UK

Fairbank J, Couper J, Davies J, O'Brien J.
The Oswestry low back pain questionnaire.
I shall discuss today...

• The overall design of the ODI
• Scoring and missing data
• Typical baseline for various conditions
• How to plot score change in a cohort
• Comparison with other outcome measures
• Criteria for success using ODI
• Translations
• Please do not use rogue versions of ODI
• How to license ODI
Preamble to ODI

• This questionnaire is designed to give us information as to how your back (or leg) trouble affects your ability to manage in everyday life.

• Please answer every section. Mark one box only in each section that most closely describes you today.
Section 1 - Pain intensity

- (0) I have no pain at the moment.
- (1) The pain is very mild at the moment.
- (2) The pain is moderate at the moment.
- (3) The pain is fairly severe at the moment.
- (4) The pain is very severe at the moment.
- (5) The pain is the worst imaginable at the moment.
ODI version 2.1a

Section 1  -  Pain intensity
Section 2  -  Personal care (washing, dressing, etc.)
Section 3  -  Lifting
Section 4  -  Walking
Section 5  -  Sitting
Section 6  -  Standing
Section 7  -  Sleeping
Section 8  -  Sex life (if applicable)
Section 9  -  Social life
Section 10 -  Travelling

(final score ranges from 0-100)
In 1980 we suggested...

- 0-20% Minimal Disability
- 20-40% Moderate Disability
- 40-60% Severe Disability
- 60-80% Crippled
- 80-100% Exaggerating or Bedbound
In 2000 we reviewed >300 citations for ‘baseline scores for various conditions’

Fairbank J, Pynsent P.
The Oswestry Disability Index.
Spine 2000;25:2940-53

N=number of subjects in each report

Mean score ±sd
Data from Fairbank J, et al. Randomised controlled trial to compare surgical stabilisation of the lumbar spine with an intensive rehabilitation programme for patients with chronic low back pain: the MRC spine stabilisation trial. BMJ., 2005;330:1233
ODI best for primary care and secondary care settings

DETERMINATION OF THE OSWESTRY DISABILITY INDEX (ODI) SCORE EQUIVALENT TO A “SATISFACTORY SYMPTOM STATE”

FAIRBANK J, VAN HOOFF ML, MANNION AF

1 Nuffield Orthopaedic Centre, Oxford University Hospitals, UK
2 Department of Research, Sint Maartenskliniek, Nijmegen, The Netherlands
3 Spine Center, Schulthess Klinik, Zürich, Switzerland
How do you measure success with ODI?

- **Achievement of a given change-score**
  - For individual subject:
    - 15-point reduction on the 0-100-scaled instrument is often used to indicate clinically-relevant change after spine surgery.
    - Adopted by FDA
  - This change
    - depends on the initial preoperative score
    - does not indicate whether a satisfactory symptom state is ultimately reached
    - Assumes linearity of ODI
- **The achievement of an absolute score equivalent to a satisfactory symptom state may be a more stringent measure of success**
- **We attempted to quantify this score for the Oswestry Disability Index (v2.1a)**
The Oswestry Low Back Pain Disability Questionnaire

JEREMY C T FAIRBANK FRCS
JUDITH COUPER MBAOT
JEAN B DAVIES MCSP DipPhysEd
JOHN P O'BRIEN PhD FRCS

Department for Spinal Disorders, Robert Jones and Agnes Hunt Orthopaedic Hospital, Oswestry, Shropshire

ONE OF THE biggest problems in assessing patients with low back pain is the lack of reliable subjective methods. Comparative measurements are possible in other musculoskeletal disorders, particularly in disabilities of the hip. Professor J Charnley uses a "green card" system routinely at Wrightington Hospital on all patients undergoing replacement arthroplasty of the hip, and a functional disability score is obtained for pain and gait. But the same difficulty of assessment has not been possible for patients with low back pain. For the last four years in Oswestry we have been developing a questionnaire which is completed by the patient and which gives us a percentage score of his level of function. By disability we mean the limitation of a patient's performance compared with that of a fit person (Garrett and Bennett, 1971). The questionnaire is printed on pink paper, since it has been found that forms on coloured paper are more readily accepted by patients (Eastwood, 1940). Clear type, capital letters and underlining (represented in print by bold lettering) all help to make the form simple to complete.

The Questionnaire

The questionnaire shown overleaf is divided into ten sections selected from a series of experimental questionnaires designed to assess limitations of various activities of daily living. The chosen sections were those found to be most relevant to patients suffering from low back pain. Each section contains six statements. This was found to be the most suitable number to obtain accurate assessments without confusing the patient. Each statement describes a greater degree of difficulty in that activity than the preceding statement. The statements are sentences which usually contain one idea and are simply worded (Bennett and Ritchie, 1972). The patient marks the one statement in each section which describes his limitations most accurately. The questionnaire takes 3 to 5 minutes to complete and about one minute to score. For patients with reading problems it may take ten minutes or more to dictate and for an assistant to complete the form. Each section is scored on a 0-5 scale, 5 representing the greatest disability. The scores for all sections are added together, giving a possible score of 50. The total is doubled and expressed as a percentage. If a patient marks two statements, the highest scoring statement is recorded as a true indication of his disability. If a section is not completed because it is inappropriate (eg Section 8 - Sex Life), the final score is adjusted to obtain a percentage.

The Oswestry low back pain disability score correlates significantly with other disability scores such as the Macnab (1975) score and the Vlaeyen (1983) score (P < 0.001). It is also capable of detecting changes which occur in patients during treatment. An example of this is shown in Figure 1 where the disability scores of 22 patients with chronic low back pain were divided into five groups. The scores were calculated for each of the sections in each of these groups. These were plotted graphically (fig 2) and demonstrate that the mean score of each of the sections tends to rise with that of the pain section, showing a good internal consistency.

Internal Consistency

To confirm that the scores of individual sections related consistently to the total disability score, the completed questionnaires of the 22 patients with chronic low back pain were divided into five groups. We calculated the mean score for the individual sections in each of these groups. These were plotted graphically (fig 2) and demonstrate that the mean score of each of the sections tends to rise with that of the pain section, showing a good internal consistency.

Interpretation of Disability Scores

0-20%: Minimal Disability

This group can cope with most of their living activities. Usually, no treatment is indicated, apart from advice on lifting, sitting posture, physical fitness and diet. In this group, some patients have particular difficulty with sitting, and this may be important if their occupation is sedentary, e.g. a typist or lorry driver.

20-40%: Moderate Disability

This group experiences more pain and problems with sitting, lifting and standing. Travel and social life are more difficult and they may well be off work. Personal care, sexual activity and sleeping are not grossly affected, and the back condition can usually be managed by conservative means.

40-80%: Severe Disability

This group has the main problem in this group of patients, but travel, personal care, social life, sexual activity and sleep are also affected. These patients require detailed investigation.

REFERENCES


Fig 1: Graph showing changes in mean disability score (LSB) with time in a group of 22 patients with primary low back pain. The three weeks significantly better than on admission (t-test P < 0.05).

Fig 2: Graphs of mean scores of individual sections of completed questionnaires grouped on percentage scores, showing relationship between pain and various activities of daily living.
Interpretation of Disability Scores

0%-20%: Minimal Disability
This group can cope with most living activities. Usually no treatment is indicated, apart from advice on lifting, sitting posture, physical fitness and diet. In this group some patients have particular difficulty with sitting, and this may be important if their occupation is sedentary, e.g., a typist or lorry driver.

20%-40%: Moderate Disability
This group experiences more pain and problems with sitting, lifting and standing. Travel and social life are more difficult and they may well be off work. Personal care, sexual activity and sleeping are not grossly affected, and the back condition can usually be managed by conservative means. A specialist may well be needed, and referral to a physiotherapist is advisable.
There are few published reports of ODI scores in the 'normal population'.

Two small biomechanical studies used back pain free controls (questionable validity in back pain free population...)


The Ste. Justine study into idiopathic scoliosis includes a telephone survey of normals published separately from the parent papers in subsequent correspondence in Spine


We have used the ODI in age matched controls to a patient population with neurogenic claudication


Together these papers give a mean score of

N=461: Mean 10.19 (SD 2.2-12)
Miranda van Hooff method*

• Mean ± 2SD= ‘normal range’
• ODI ‘Normal range’ is ≤22

• *van Hooff M, et al.

Predictive factors for successful clinical outcome one year after an intensive combined physical and psychological programme for chronic low back pain

Functional status as measured with the ODI (0-100) in the RealHealthNL study sample (n=524).
Oxford Tango Series
Anne Mannion Analysis

• 532 patients undergoing lumbar spine surgery
• All completed the ODI and the Core Outcome Measures Index (COMI) at various times up to 4y after surgery.
• The COMI item: “if you had to spend the rest of your life with the symptoms you have right now, how would you feel about it?” was responded to on a 5-point Likert scale from “very satisfied” to “very dissatisfied”.
Oxford Tango Series
Anne Mannion Analysis

• 5-point Likert scale from “very satisfied” to “very dissatisfied”.

• Two receiver operating characteristics (ROC) analyses were used to derive cut-off scores for ODI that best predicted being:

1) “somewhat satisfied” with the symptom state

2) “very satisfied” with the symptom state
Results

• Satisfaction with symptom state
  • 114/532 (21%) ‘≥ somewhat satisfied’
  • 43/532 (8%) ‘very satisfied’

• ROC area under the curve
  ‘≥ somewhat satisfied’
  0.89 (95% CI, 0.86-0.92)
  ‘very satisfied’
  0.94 (95% CI, 0.92-0.96)
ROC cut-off scores

• The ODI-score cut-off predicting “≥somewhat satisfied state”
  • ≤ 29 points (sensitivity 88%; specificity 75%)

• The ODI-score cut-off predicting “very satisfied state”
  • ≤ 14 points (sensitivity 86%; specificity 89%)
Discussion

...when assessing the success of surgery.

• **Change** scores reflect improvement after treatment
  - They may give a more optimistic view than when the proportion of patients achieving a satisfactory state is examined

• With limited availability of valid “norm values” for condition-specific questionnaires, the % patients reaching an ODI score equivalent to a **satisfactory state** might represent a more appropriate criterion
Conclusion

• ODI “normal” criterion:
  – I favour <22 ODI points as being ‘compatible with normal life’

• More work is needed on this
Abschnitt 10 - Reisen/Fahrten

- Ich kann überallhin reisen, ohne Schmerzen zu bekommen.
- Ich kann überallhin reisen, aber die Schmerzen werden dadurch stärker.
- Trotz starker Schmerzen kann ich länger als 2 Stunden unterwegs sein.
- Ich kann auf Grund von Schmerzen höchstens 1 Stunde unterwegs sein.
- Ich kann auf Grund von Schmerzen nur kurze notwendige Fahrten unter 30 Minuten machen.
- Schmerzen hindern mich daran, Fahrten zu machen, außer zur medizinischen Behandlung.
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Linguistic Validation Methodology

1. Conceptual analysis of source questionnaire in collaboration with the developer
2. Forward translation
3. Backward translation
4. Cognitive interviews/Clincian review
5. Proofreading and finalization
Linguistic Validation Methodology

**Step**
- Conceptual analysis of source questionnaire in collaboration with the developer

**Decision-Making Process**
- 2 Forward translations
- Backward translation
- Cognitive interviews and Clinician review
- Proofreading and finalization

**Outcomes**
- List of concepts for harmonization of translations across countries
- Target Language Version 1
- Target Language Version 2
- Target Language Version 3
- Final Target Language Version

**Participants/language**
- **Coordinating centre - Mapi**
- **Developers**
- **Coordinating centre - Mapi**
- **In-country Consultant**
- **2 Translators**
- **Coordinating centre - Mapi**
- **In-country Consultant**
- **1 Translator**
- **Coordinating centre - Mapi**
- **In-country Consultant**
- **5 Subjects + Clinician**
- **Coordinating centre - Mapi**
- **In-country Consultant**
- **1 Translator**

**Linguistic Validation Certificate**

**Report**
Conclusion - Key message

• **Aim:** Obtain high-quality translations suitable for use in international clinical studies.

• **Means:** Standardized, internationally recognized linguistic validation process that fully meets the requirements of health authorities.

• **Outcome:** Translations of ODI that are:
  – Conceptually equivalent to original instrument
  – Culturally relevant and acceptable to the target population within each country
  – Clear and easy to understand by the target population
  – Consistent and comparable across languages

• **Performing new translations**
  – **Academic Translation:** Contact Mapi Research Trust to sign a translation agreement and to obtain Linguistic Validation Guidelines.
  – **Commercial Users:** Exclusive vendor for translation work for commercial users: Mapi Linguistic Validation.
Please do not use Rogue ODI’s

- Chiropractic
- “modified”
- Hindi modified etc etc
Surgical treatment of back pain
Baseline scores
Surgical treatment of back pain
Baseline scores

ODI Score

- 65
- 60
- 55
- 50
- 45
- 40

55% and 40% as baseline scores

Graph showing various studies such as Fairbank (surgery), Fairbank (Rehab), Brox, Zigler (Fusion), Zigler (ProDisc), Fritzell (fusion), Fritzell (non-op), Blumenthal (control), Blumenthal (invest).
Chiro ODI.....

Zigler, J; Delamarter, R; Spivak, J; Linovitz, RJ; Danielson, GO; Haider, TT; Cammisa, F; Zuchermann, J; Balderston, R; Kitchel, S; Foley, K; Watkins, R; Bradford, D; Yue, J; Yuan, H; Herkowitz, H; Geiger, D; Bendo, J; Peppers, T; Sachs, B; Girardi, F; Kropf, M; Goldstein, J.

Results of the Prospective, Randomized, Multicenter Food and Drug Administration Investigational Device Exemption Study of the ProDisc(R)-L Total Disc Replacement Versus Circumferential Fusion for the Treatment of 1-Level Degenerative Disc Disease.

Spine 2007;32(11):1155-1162
Section 10—Changing degree of pain
My pain is rapidly getting better. My pain fluctuates but overall is definitely getting better.
My pain seems to be getting better but improvement is slow at present.
My pain is neither getting better or worse. My pain is gradually worsening. My pain is rapidly worsening.
Original article

Rasch analysis of three versions of the Oswestry Disability Questionnaire

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Received 11 October 2006; received in revised form 9 January 2007; accepted 17 January 2007

Abstract

The purpose of the study was to explore the construct validity of three versions of the Oswestry Disability Questionnaire for low back pain using Rasch analysis. The three versions of the ODQ share 9 items and differ on one other. About 100 patients with non-specific low back pain seeking physiotherapy treatment at hospital outpatient departments and physiotherapy private practices completed the 12 Oswestry items as part of a battery of questionnaires. Rasch analysis revealed that four items (Personal Care, Standing, Sex Life and Social Life) had disordered response thresholds and one item (Walking) showed differential item functioning by age. The 10 standard Oswestry items and a modified version in which Sex Life is replaced by Work/Housework showed adequate overall fit to the Rasch model ($\chi^2 P > .01$). The third version, in which Sex Life is replaced...
Use and Abuse of Oswestry Disability Index

Jeremy C. T. Fairbank, MD, FRCS

Readers of this journal are well aware of the difficulties we have in measuring clinical outcomes in back pain research. The instruments we have are flawed despite the sterling efforts of many investigators. Although it is essential we continue to develop improved outcome measures, it is important to care for the ones we have in active use. The Oswestry Disability Index (ODI) was first published 27 years ago. Since then it has become one of the leading condition-specific outcome measures in back pain research and clinical practice. In that time, like most such outcome instruments, various modifications have been made. It has been used on a similar basis to computer “freeware.” The original authors have only sought a royalty when it has been sold as part of a marketed package. As lead author of the original publication, I have tried to keep it clean and reliable. Many studies have been published comparing it to other instruments and investigating its reliability. It has been translated into many languages, and these translations have lead to further validation studies.\(^1,2\) I have listed all the available versions in English and translations on a website http://www.orthosurg.org.uk/odi/.

In 1998, I performed a citation review of the use of ODI, which led to a publication with Paul Pynsent.\(^3\) This included what we called ODI (v2.0), which had a modification of the pain question (Q1), and clarification of the wording of other sections developed for a chiropractors but never validated. It was my mistake to allow the use of the term “revised Oswestry Pain Questionnaire” and I now consider this to be in breach of the copyright held by the authors of the original publication.

I was not aware of any major study where this chiropractic version has been used, until the FDA Device Exemption Study of the ProDisc-L Total Disc Replacement was published this year.\(^6\) Their use of this questionnaire has demonstrated why care with instruments is so important.\(^6\)a There are 4 main issues:

**Validation.** Zigler’s response\(^6\) at the end of this edition of SPINE would suggest that quoting a reference from an un refereed book (that readers will only be able obtain with the greatest difficulty), quoting no validation studies, and stating that the chiropractic questionnaire is “essentially the same,” seems to fly in the face of the obsessive work of investigators, referees and editors to get ODI and other outcome measure as inch perfect as possible.

**Version Numbers.** Zigler et al’s publication does not indicate which version of the “Oswestry Disability Index” was used. It is not alone. It is essential that investigators indicate the version number of an instrument in publications and that this practice is enforced by editors and referees.
Publications on abuse of ODI


http://www.proqolid.org/instruments/oswestry_disability_index_odi

- Copyright holders have licensed MAPI to care for ODI
- No cost to clinical users, but do need to sign agreement
- Some costs for translations and for commercial users.
- Check MAPI Trust website for correct versions and translations
- contact@mapi-trust.org
- Use version ODI v2.1a
I have discussed...

• The overall design of the ODI
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