Oswestry Disability Index

To the Editor: I welcome the publication of the 5-year follow-up of the ProDisc FDA investigational device exemption (IDE) study9,10 (Zigler JE, Delamarter RB: Five-year results of the prospective, randomized, multicenter, Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential arthrodesis for the treatment of single-level degenerative disc disease. Clinical article. J Neurosurg Spine 17:493–501, December 2012; Zigler JE, Glenn J, Delamarter RB: Five-year adjacent-level degenerative changes in patients with single-level disease treated using lumbar total disc replacement with ProDisc-L versus circumferential fusion. Clinical article. J Neurosurg Spine 17:504–511, December 2012). What I do not welcome is the use of the term “Oswestry Disability Index” (ODI) in relation to the outcome measure used in this study. “ODI” is used without any references at all in the paper on adjacent-level changes,10 nor are there any references in that paper to the main 5-year outcome paper,9 which precedes it, so the reader may be forgiven for believing that the outcome measure used was a fully validated version of the ODI.

This is not the case, as was made clear following the report of the 2-year results of the ProDisc study.2 This fact is well known to the authors, who have chosen to conceal the details of the questionnaire they used from the readers of the second of the 5-year outcome papers (the paper on adjacent-level degenerative changes).10 However, I accept that the ODI reference is to the Hudson-Cook chapter7 as cited by Zigler and Delamarter in the first of the two 5-year results papers published in the Journal of Neurosurgery: Spine.9 Hudson-Cook et al. called their questionnaire “A revised Oswestry disability questionnaire.” This title or reference was never adopted in Zigler’s original publications, so that it was only by diligent research that I was able to identify the actual questionnaire they had used. I suspect, but cannot prove, that the ProDisc investigators used the text of the Hudson-Cook et al. questionnaire found in our publication,3 where we made clear the inadequacies of this chiropractic revision, as we called it, which they chose to ignore. In the correspondence following their 2007 publication, Zigler claimed “The differences between the various ODI versions are subtle and, we think, inconsequential.”2 This is patently not the case: The questionnaire they used is compared directly with ODI version 2.1a in Fig. 1. Differences in conception are shown in red type, and sections with major differences in wording are highlighted in yellow. As far as I can identify, the Hudson-Cook/Chiropractic/Zigler questionnaire has never been used in any other large-scale study of spinal disorders, let alone an FDA-IDE study.

Any reader can see that this questionnaire is extremely different in wording and conception from ODI 2.1a, the current version of ODI, which is directly descended from the original.6 A Rasch analysis conducted by Davidson1 confirmed that the Zigler questionnaire behaves very differently from other validated ODI versions, with their “Changing Degree of Pain” item measuring a different underlying construct. To my knowledge, this is the only report in a peer-reviewed journal examining the validity of this questionnaire. The Hudson-Cook et al. questionnaire was only reviewed by the editors of the textbook in which their paper was published; perhaps Zigler can offer alternative evidence that the questionnaire they used had external peer review or indeed any validation at all?

It is therefore not surprising that the “ODI scores” presented in these papers are so different from the results of many other large well-designed studies of chronic back pain populations that used a validated version of the ODI as an outcome measure.4 Moreover, the use of the term ODI is inappropriate for this Hudson-Cook et al. version and probably in breach of copyright of the original publication.6

I suggest that the reasons the authors persist in using the term “ODI” are because a validated version of this outcome measure is required by the FDA for the IDE study; comparative studies with other surgical interventions for back pain are essential for understanding this study, and for their commercial sponsors. The authors of at least 1 systematic review have identified that the ProDisc IDE study did not use a validated version of the ODI.8

The ODI has an international reputation and is widely used in back pain research as a primary outcome measure. It is used to compare the results of well-designed studies. By originally concealing the nature of the instrument used in their study, Zigler and colleagues have damaged the reputation of the ODI and adversely affected our capacity to understand the benefits of their intervention.2

The honorable action would be for the authors to withdraw their papers and represent their findings without reference to Oswestry or the ODI at all.

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This article contains some figures that are displayed in color online but in black-and-white in the print edition.
Fig. 1. Comparison of the questionnaire used by Zigler and colleagues (left) and the Oswestry Disability Index v2.1a (right). Differences in conception are indicated by red type, and sections with major differences in wording are highlighted in yellow. Note that Section 8 (present in ODI v2.1a and highlighted in this image) is absent from the questionnaire on the left. The questionnaire on the left is from Hudson-Cook et al.7 Used here with permission from Manchester University Press.