Oswestry Disability Index

To the Editor: I welcome the publication of the 5-year follow-up of the ProDisc FDA investigational device exemption (IDE) study (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, nor are there any references in that paper to the main 5-year outcome paper, 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. 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). However, I accept that the ODI reference is to the Hudson-Cook chapter as cited by Zigler and Delamarter in the first of the two 5-year results papers published in the Journal of Neurosurgery: Spine. 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, 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.” 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. A Rasch analysis conducted by Davidson 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. 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.

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.

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.

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.
Table 1. Comparison of the questionnaire used by Zigler and colleagues (left) and the Oswestry Disability Index v2.1a (right).

<table>
<thead>
<tr>
<th>Section</th>
<th>Zigler et al Questionnaire</th>
<th>Oswestry Disability Index v2.1a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 1 - Pain intensity</td>
<td>The pain was severe and very painful. The pain is moderate and not very much. The pain is not moderate and is moderate. The pain is not severe and is mild. The pain is severe and not very severe.</td>
<td>Pain intensity. The pain is very severe at the moment. The pain is moderate at the moment. The pain is severe at the moment. The pain is very mild at the moment.</td>
</tr>
<tr>
<td>Section 2 - Personal care</td>
<td>I do not have any difficulties in washing or dressing in order to avoid pain. I do not have any difficulties in washing or dressing even though it causes some pain. Washing and dressing increases the intensity of the pain. I do not have any difficulties in washing or dressing even though it causes some pain. Washing and dressing increases the intensity of the pain.</td>
<td>Personal care (washing, dressing, etc.) I can carry out my normal activities without causing extra pain. I can carry out my normal activities with some discomfort. I need some help to carry out my personal care.</td>
</tr>
<tr>
<td>Section 3 - Lifting</td>
<td>I can lift heavy weights without extra pain. I can lift heavy weights but I plan extra pain.</td>
<td>Lifting. I can lift heavy weights without extra pain. I can lift heavy weights but I plan extra pain.</td>
</tr>
<tr>
<td>Section 4 - Walking</td>
<td>I have no pain on walking. I have some pain on walking but it is not severe. I cannot walk even if I use a walking stick. I cannot walk more than 100 meters.</td>
<td>Walking. I can walk first 1200 meters without pain. I can walk more than 1000 meters but I need pain medication. I cannot walk more than 100 meters.</td>
</tr>
<tr>
<td>Section 5 - Sitting</td>
<td>I can sit on my chair as long as I like. I can sit in my favorite chair as long as I like.</td>
<td>Sitting. I can sit in my chair as long as I like. I can sit in my favorite chair as long as I like.</td>
</tr>
<tr>
<td>Section 6 - StANDING</td>
<td>I am able to stand for more than 60 minutes. I am able to stand for more than 1 hour. I am able to stand for more than 15 minutes.</td>
<td>Standing. I can stand for more than 60 minutes. I can stand for more than 1 hour. I can stand for more than 10 minutes.</td>
</tr>
<tr>
<td>Section 7 - Sleeping</td>
<td>I go to sleep easily. I go to sleep easily and I do not have any difficulties in sleeping.</td>
<td>Sleeping. I can go to sleep easily. I can sleep for more than 6 hours.</td>
</tr>
<tr>
<td>Section 8 - Social life</td>
<td>My social life is normal and given pain.</td>
<td>Social life. My social life is normal and given pain.</td>
</tr>
<tr>
<td>Section 9 - Travelling</td>
<td>I go to pain whilst travelling. I go to pain whilst travelling but it does not cause me to seek alternative forms of travel. I go to pain whilst travelling which compels me to seek alternative forms of travel.</td>
<td>Travelling. I can travel anywhere without pain. I can travel anywhere without pain. I cannot travel anywhere without pain.</td>
</tr>
</tbody>
</table>

**Note:** 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. Used here with permission from Manchester University Press.
Neurosurgical forum

Disclosure

As one of the ODI copyright holders, the author derives income from licensing of the ODI to commercial users.

References


RESPONSE: We acknowledge Mr. Fairbank’s comments regarding our articles Two-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. and 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. Mr. Fairbank made very similar comments following our publication of the 2-year IDE data in 2007. We appreciate his long interest in protecting the integrity of the ODI, a commonly utilized instrument developed initially by Mr. J. P. O’Brien and the Oswestry group in 1976. We have no desire to depreciate Mr. Fairbank’s contribution to this work, nor his clinical research on the same. However, we do feel that the magnitude of his objection to the use of a modified version is misguided. As addressed in our response to his similar comments regarding our initial paper, we felt that the use of the modified version of the ODI, published in 1989 and approved by the FDA in 2001 for use in this study, was reasonable and appropriate.

We agree that the version we used differs from versions used in IDE studies for other manufacturers’ implants, which certainly makes it difficult for direct comparison or for pooling of data. We have also previously addressed that issue in our response to Mr. Fairbank in 2007 and agreed that a uniform scoring instrument, be it the ODI or a newer validated instrument, should be used in all future clinical research. However, we would strongly object to excluding the modified version of the ODI as part of the 5-year follow-up data described in this paper. We feel that it would be highly inappropriate if the longer-term results excluded any part of the original outcome measures, despite Mr. Fairbank’s comments regarding the version used.

Within our own study, the fact that ODI improvement was only 1 of 10 success end points, that it was used similarly by both investigational and control cohorts, and that only the delta (the change from preoperative baseline to 24-month data points) was used for calculation should make the subtle, and generally semantic, differences between versions of the ODI clinically insignificant.

As a clinical investigator invited to participate in, and later report for, the ProDisc-L study, I take some umbrage at Mr. Fairbank’s referring to the “Zigler questionnaire.” I actually had no part in the design of the ProDisc-L IDE study or the selection of the ODI version used. My involvement with the project occurred well after the FDA had approved the study design. The instrument version used in the ProDisc-L study is no more the “Zigler questionnaire” than the ODI is the “Fairbank questionnaire.” The 2-year and 5-year clinical results of the ProDisc-L IDE study represent some of the most meticulously and accurately acquired and published data describing the outcomes of surgical intervention for functionally disabling lumbar disc disease. The authors proudly stand behind the thousands of hours of work, performed by hundreds of individuals, that ultimately resulted in its published findings. We are confident that Mr. Fairbank’s objections are irrelevant to the overall outcomes as reported and are not shared by the great majority of readers.

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References

Combining internal fixation with vertebroplasty


Vertebroplasty was first introduced in 1987 by Galibert el al. for treating spinal hemangioma. Now it is often used to treat osteoporosis fractures. Nowadays the utility of vertebroplasty is rapidly becoming known the world over, although controversy remains.

This study by Gu et al. illustrated a new technique combining vertebroplasty with the minimal internal fixation to treat thoracolumbar osteoporosis fracture. They concluded that the new combined technique could reduce the occurrence of new vertebral compression fractures (VCFs) after vertebroplasty. We appreciate the effort the authors had made to develop a new technique, but we still have some questions.

First, although the vertebroplasty technique is a minimally invasive operation and can relieve a patient’s pain within the first few postoperative days, opponents of the technique still contend that the cement injected into the spinal vertebra increases the stiffness and changes the biomechanical mechanism of force transfer, which might finally lead to a new adjacent vertebral fracture. Many researchers like Gu et al. and Lu and Yang have combined vertebroplasty with internal fixation to treat osteoporosis fracture in older patients; both groups have concluded that this technique protects patients from the new adjacent vertebral fracture beyond pain relief. However, recently, several meta-analyses have asserted that vertebroplasty alone did not increase the number of new adjacent vertebral fractures in the follow-up, which means that combining both surgeries to reduce the risk of new VCFs is not necessary.

Second, even when using expandable pedicle screws, internal fixation for the osteoporotic fracture is still a challenge for doctors. The pedicle screw pullout rate in older patients is much higher than that in younger patients due to older patients’ poor bone mineral density, and the risk of adjacent-structure injury increases compared with simple vertebroplasty when performing minimal internal fixation. Although Gu et al. reported no hardware failure or additional injuries during the operations and follow-up, we still believe, based previous reports, that it is not appropriate to apply the standard internal screws in the minimally invasive approach in older patients.

What’s more, as we know, internal fixation is expensive. Since combining vertebroplasty and internal fixation may not reduce the rate of new VCFs, the high cost of internal fixation is not reasonable.

Because there is no additional research to support the application of these two surgeries in patients with osteoporosis fractures, the role of combined surgery in older patients is still being defined, and we think that it is not necessary to combine these two procedures.

We await further study from the authors.

Disclosure

The authors report no conflict of interest.

References

8. Lu C, Yang M: [Posterior pedicle screw fixation with vertebro-


RESPONSE: We appreciate Drs. Tong and Wu for raising interesting questions about the surgical treatment of thoracolumbar osteoporotic VCFs.

New VCFs after percutaneous vertebroplasty (PVP) or percutaneous kyphoplasty (PKP) include not only newly developed fracture in adjacent vertebrae, but also further compression of previously operated vertebrae with no additional trauma. Tong and Wu only mentioned new adjacent vertebral fracture. There are a few contributing factors to new VCFs after PVP or PKP; these include age, bone mineral density, the presence of preoperative osteonecrosis, intervertebral cleft, preexisting fracture, treatment modality, amount of cement injected, restoration rate of vertebral height, non-polymethylmethacrylate-endplate contact, and intradiscal cement leakage. We do not think that the injection of cement into the spinal vertebra, which increases stiffness and changes the biomechanical mechanism of force transfer, is the only cause of new adjacent vertebral fracture. In addition, based on the references to meta-analyses cited by Tong and Wu, it is not easy to conclude that vertebroplasty would not increase the rate of new adjacent vertebral fractures during follow-up. For example, in the study by Ma et al.,1 the authors found that there were no significant differences in adjacent vertebral fracture rates between balloon PKP and PVP, but the results of PVP or PKP were not compared with nonoperative intervention. Ma et al. also realized that, because of the poor quality of the evidence currently available, high-quality randomized controlled trials are required. In our study, we designed a technique to combine minimally invasive pedicle screw fixation with PVP to treat thoracolumbar osteoporotic VCFs because there is evidence that new VCFs occur after PVP. Lavelle and Cheney reported that the incidence of recurrent fracture at the operated level was 10% after PKP. Kim and Ryu showed that the incidence of recompensation in treated vertebral was 12.5%. Jensen and Dion reported that the rate of new adjacent vertebral fractures after PVP ranged from 20% to 25%. Kim et al. found that 51.9% of 114 patients who underwent PVP subsequently suffered an adjacent vertebral fracture. Rho et al. reported that 27 (18.4%) of 147 patients treated with PVP or PKP had symptomatic new VCFs and that in 66.7% of the 27 patients a new VCF of the adjacent vertebra developed. Whether vertebroplasty would increase the rate of new adjacent vertebral fractures was not included in our discussion.

Short-segment pedicle screw instrumentation is a well-described technique to reduce and stabilize thoracic and lumbar spinal fractures. However, hardware failure and a loss of reduction are recognized complications caused by insufficient anterior column support even in young patients in whom resistance to pedicle screw pullout is high. It is known that cement-based vertebroplasty can restore, even increase, strength and stiffness after VCFs in osteoporotic specimens. In a cadaveric biomechanical study by Mermelstein et al., the authors found that the injection of cement into a burst fracture reduced the load on the pedicle screw construct that was inserted for fracture stabilization, and cement-based vertebroplasty after insertion of posterior instrumentation might reduce hardware failure and anterior column collapse. This conclusion was also supported by the results of our study in which there is no hardware failure in any patient during follow-up after instrumentation insertion and PVP, although the mean age in the patient population was 73.6 years. These data gave us more confidence to use pedicle screw fixation in elderly patients. Currently, we are performing further studies to compare this technique with PVP, PKP, and nonoperative controls. Even if expandable pedicle screw or cement-augmented pedicle screw fixation is used, the technique of minimally invasive pedicle screw fixation is still available through minimal access in a paraspinal sacrospinalis muscle-splitting (Wilke) approach.

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References


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