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[9,10] (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 chapter[7] 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,[5] 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 Davidson[1] 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.[3]

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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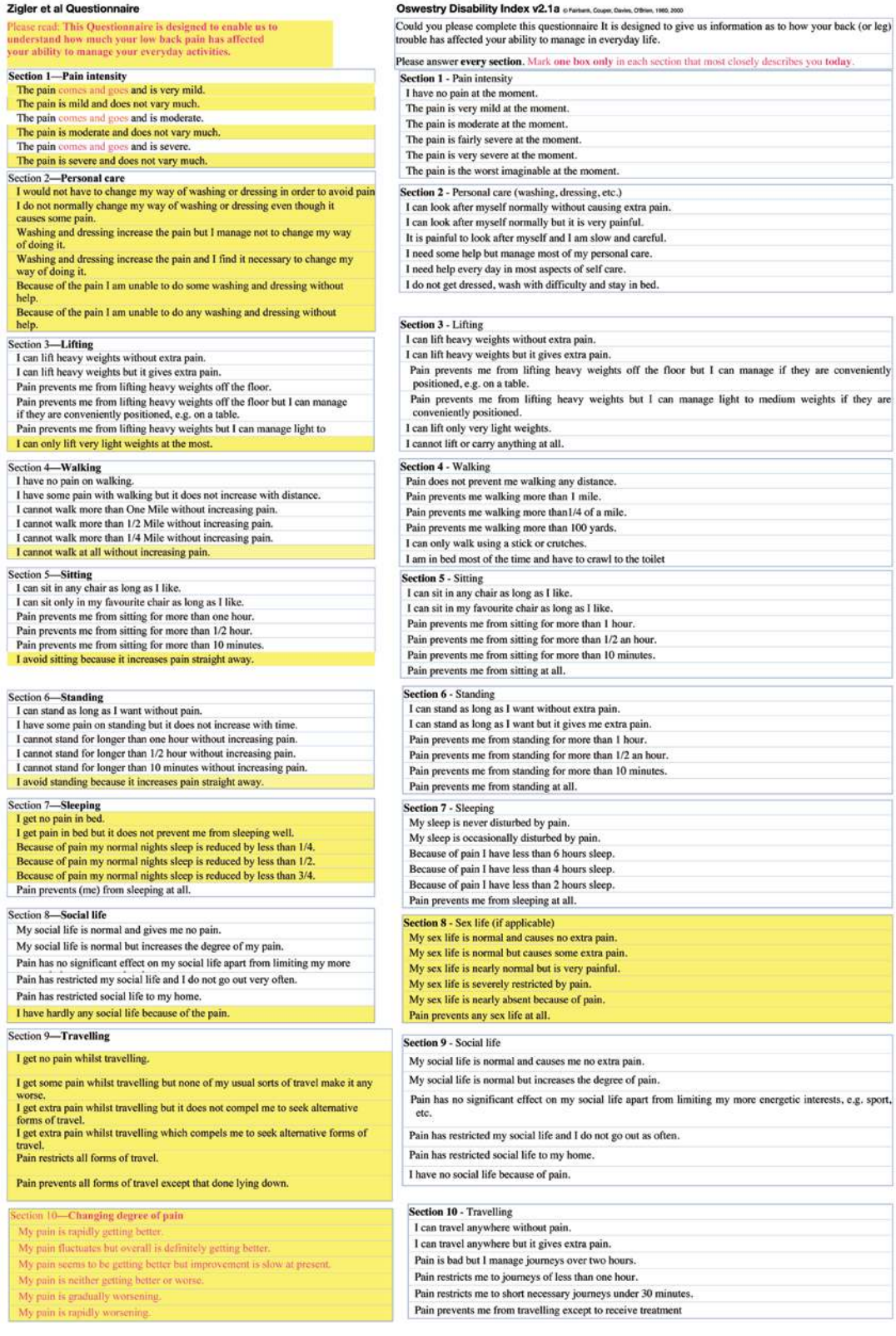
This article contains some figures that are displayed in color online but in black-and-white in the print edition.



Zigler et al Questionnaire

Please read: **This Questionnaire is designed to enable us to understand how much your low back pain has affected your ability to manage your everyday activities.**

Section 1—Pain intensity
- The pain comes and goes and is very mild.
- The pain is mild and does not vary much.
- The pain comes and goes and is moderate.
- The pain is moderate and does not vary much.
- The pain comes and goes and is severe.
- The pain is severe and does not vary much.

Section 2—**Personal care**
- I would not have to change my way of washing or dressing in order to avoid pain
- I do not normally change my way of washing or dressing even though it causes some pain.
- Washing and dressing increase the pain but I manage not to change my way of doing it.
- Washing and dressing increase the pain and I find it necessary to change my way of doing it.
- Because of the pain I am unable to do some washing and dressing without help.
- Because of the pain I am unable to do any washing and dressing without help.

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.
- Pain prevents me from lifting heavy weights off the floor but I can manage if they are conveniently positioned, e.g. on a table.
- Pain prevents me from lifting heavy weights but I can manage light to
- I can only lift very light weights at the most.

Section 4—**Walking**
- I have no pain on walking.
- I have some pain with walking but it does not increase with distance.
- I cannot walk more than One Mile without increasing pain.
- I cannot walk more than 1/2 Mile without increasing pain.
- I cannot walk more than 1/4 Mile without increasing pain.
- I cannot walk at all without increasing pain.

Section 5—**Sitting**
- I can sit in any chair as long as I like.
- I can sit only in my favourite chair as long as I like.
- Pain prevents me from sitting for more than one hour.
- Pain prevents me from sitting for more than 1/2 hour.
- Pain prevents me from sitting for more than 10 minutes.
- I avoid sitting because it increases pain straight away.

Section 6—**Standing**
- I can stand as long as I want without pain.
- I have some pain on standing but it does not increase with time.
- I cannot stand for longer than one hour without increasing pain.
- I cannot stand for longer than 1/2 hour without increasing pain.
- I cannot stand for longer than 10 minutes without increasing pain.
- I avoid standing because it increases pain straight away.

Section 7—**Sleeping**
- I get no pain in bed.
- I get pain in bed but it does not prevent me from sleeping well.
- Because of pain my normal nights sleep is reduced by less than 1/4.
- Because of pain my normal nights sleep is reduced by less than 1/2.
- Because of pain my normal nights sleep is reduced by less than 3/4.
- Pain prevents (me) from sleeping at all.

Section 8—**Social life**
- My social life is normal and gives me no pain.
- My social life is normal but increases the degree of my pain.
- Pain has no significant effect on my social life apart from limiting my more
- Pain has restricted my social life and I do not go out very often.
- Pain has restricted social life to my home.
- I have hardly any social life because of the pain.

Section 9—**Travelling**
- I get no pain whilst travelling.
- I get some pain whilst travelling but none of my usual sorts of travel make it any worse.
- I get extra pain whilst travelling but it does not compel me to seek alternative forms of travel.
- I get extra pain whilst travelling which compels me to seek alternative forms of travel.
- Pain restricts all forms of travel.
- Pain prevents all forms of travel except that done lying down.

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.

Oswestry Disability Index v2.1a © Fairbank, Couper, Davies, O'Brien, 1980, 2000

Could you please complete this questionnaire It is designed to give us information as to how your back (or leg) trouble has affected 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
- I have no pain at the moment.
- The pain is very mild at the moment.
- The pain is moderate at the moment.
- The pain is fairly severe at the moment.
- The pain is very severe at the moment.
- The pain is the worst imaginable at the moment.

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 is very painful.
- 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, e.g. 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 than1/4 of a mile.
- Pain prevents me walking more than 100 yards.
- 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 sit in my favourite chair as long as I like.
- Pain prevents me from sitting for more than 1 hour.
- Pain prevents me from sitting for more than 1/2 an hour.
- Pain prevents me from sitting for more than 10 minutes.
- Pain prevents me from sitting at all.

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 an hour.
- Pain prevents me from standing for more than 10 minutes.
- Pain prevents me from standing at all.

Section 7 - Sleeping
- My sleep is never disturbed by pain.
- My sleep is occasionally disturbed by pain.
- Because of pain I have less than 6 hours sleep.
- Because of pain I have less than 4 hours sleep.
- Because of pain I have less than 2 hours sleep.
- Pain prevents me from sleeping at all.

Section 8 - Sex life (if applicable)
- 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 causes 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, e.g. sport, etc.
- Pain has restricted my social life and I do not go out as often.
- Pain has restricted social life to my home.
- I have no social life because of pain.

Section 10 - Travelling
- I can travel anywhere without pain.
- I can travel anywhere but it gives 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 under 30 minutes.
- Pain prevents me from travelling except to receive treatment

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.

Disclosure

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

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Response: We acknowledge Mr. Fairbank's comments regarding our articles "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."[5] 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."[6] Mr. Fairbank made very similar comments following our publication of the 2-year IDE data in 2007.[1]

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.[2] 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,[1,4] 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.[3]

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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Combining internal fixation with vertebroplasty

To The Editor: We read with great interest the article by Gu et al.[5] (Gu Y, Zhang F, Jiang X, et al: Minimally invasive pedicle screw fixation combined with percutaneous vertebroplasty in the surgical treatment of thoracolumbar osteoporosis fracture. Clinical article. *J Neurosurg Spine 18:*634–640, June 2013).

Vertebroplasty was first introduced in 1987 by Galibert el al. for treating spinal hemangioma.[4] 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.[3,6] Many researchers like Gu et al.[5] and Lu and Yang[8] 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,[1,9,11,13] 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.[2] 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.[7] Although Gu et al. reported no hardware failure or additional injuries during the operations and follow-up, we still believe, based previous reports,[2,7,10,12] 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.

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Disclosure

The authors report no conflict of interest.

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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[7,8,14,19] but also further compression of previously operated vertebrae[6,9,10,12,13] 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.[7,8,10,19] 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[1,15,20,22] 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.,[15] 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.[6–10,12–14,19] Lavelle and Cheney[12] reported that the incidence of recurrent fracture at the operated level was 10% after PKP. Kim and Rhyu showed that the incidence of recompression in treated vertebrae was 12.5%.[10] Jensen and Dion[7] and Liebschner et al.[14] reported that the rate of new adjacent vertebral fractures after PVP ranged from 20% to 25%. Kim et al.[8] 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.[19] 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.[4,18] However, hardware failure and a loss of reduction are recognized complications caused by insufficient anterior column support,[11,16] 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.[2,3,5] 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,[17] 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 (Wiltse) approach.[21]

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