

Percutaneous Vertebroplasty for Osteoporotic Compression Fractures: Quantitative Prospective Evaluation of Long-term Outcomes

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PURPOSE: Osteoporotic vertebral compression fractures may cause debilitating pain that lasts for weeks or months, and which is often neither quickly nor completely relieved by conventional conservative therapy. Previous retrospective studies have suggested significant and nearly immediate pain relief, as well as rapid and sustained functional recovery, after percutaneous polymethylmethacrylate vertebroplasty (PPV). This prospective, quantitative study with long-term follow-up was designed to evaluate the safety and efficacy of PPV as a new treatment for patients with osteoporotic vertebral body compression fractures of the lumbar and thoracic spine.

MATERIALS AND METHODS: PPV was performed in 30 patients with 54 symptomatic osteoporotic vertebral compression fractures who had a less-than-satisfactory response to conventional therapy. All procedures were performed by a single operator with significant experience in performing PPV. The Musculoskeletal Outcomes Data Evaluation and Management Scale (MODEMS) spinal intervention questionnaire, which includes the SF-36, was administered to all patients before intervention and exactly 2 weeks after the final PPV procedure. Pain and disability, treatment expectations and satisfaction, mental function, and quality of life were evaluated by four specialized modules, and responses to questionnaires preceding treatment were compared to those obtained at follow-up. Results of a long-term follow-up questionnaire were collected 15–18 months after the final vertebroplasty treatment.

RESULTS: Our population consisted of three men and 27 women, with a mean age of 79 years. Fifty-four PPV procedures were performed for compression fractures in these 30 patients. Significant postprocedural improvement in all four MODEMS modules was demonstrated at 2 weeks (treatment score, $P < .0001$; pain and disability, $P < .0001$; physical function, $P = .0004$; and mental function, $P = .0009$). A small epidural leak of polymethylmethacrylate in one patient was asymptomatic and did not require intervention. At long-term follow-up (15–18 mo), 22 of 23 patients responding remained satisfied with the outcome of therapy and believed that the procedure had provided durable pain relief. Verbal pain scores documented significantly diminished back pain at 2 weeks ($P < .0001$) and again at long-term follow-up when compared to baseline ($P < .0001$).

CONCLUSIONS: PPV is a safe and efficacious procedure for the relief of pain and disability after osteoporotic vertebral compression fractures. Patient satisfaction is high and persists when compared to preprocedural expectations; durable pain relief is provided.

Index terms: Osteoporosis • Spine, fractures • Vertebroplasty

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Abbreviations: MODEMS = Musculoskeletal Outcomes Data Evaluation and Management Scale, PMMA = polymethylmethacrylate, PPV = percutaneous polymethylmethacrylate vertebroplasty

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OSTEOPOROSIS, characterized by low bone mass and structural deterioration of bone tissue leading to fragility, is the most prevalent metabolic bone disease and is often the cause of compression fractures in the elderly (1,2). Osteoporosis is estimated to afflict 200 million women worldwide (3), and in the United States affects

45% of women and 13% of men older than 50 years of age (4). Osteoporosis is responsible for more than 1.5 million fractures annually in the United States; nearly half these are fractures of the vertebral bodies (5–7). The annual cost of health care and lost productivity caused by osteoporosis exceeded 10 billion dollars in 1994 in the United States alone (2). Therefore, we sought to evaluate a minimally invasive procedure that could provide internal splinting and structural support for a partially compressed vertebral body, with the goal of decreasing impairment and subsequent morbidity.

Percutaneous polymethylmethacrylate vertebroplasty (PPV), the augmentation of fractured or fragile vertebral bodies with use of the bone cement polymethylmethacrylate (PMMA), has grown in popularity since it was first introduced in the United States at the annual meeting of the Radiological Society of North America in 1988 (8). Variations of PPV with use of PMMA or cyanoacrylate have been reported to be successful in treating vertebral compression fractures related to osteoporosis (9–11), in the treatment of metastases and myeloma (12–14), and for relief of pain and control of perioperative blood loss in vertebral hemangiomas (13,15–18). PPV has also been used successfully to treat patients who were debilitated by steroid-induced osteoporotic compression fractures, and has been performed at numerous levels in the same patients (19). However, to our knowledge, only one study has used an accepted and previously validated scale to prospectively determine the efficacy of this novel therapy (20). Long-term follow-up has been only rarely and inconsistently reported (20–24). In this investigation, we used a data evaluation and outcomes system, the Musculoskeletal Outcomes Data Evaluation and Management Scale (MODEMS), which was developed in conjunction with the American Academy of Orthopedic Surgeons to evaluate the outcomes of surgical spine intervention, to determine the efficacy of PPV (25–27). A follow-up questionnaire that included verbal pain score scales was used to assess the durability of results 15–18 months after PPV.

This prospective, quantitative study with long-term follow-up was designed to evaluate the safety and

efficacy of PPV as a new treatment for patients with painful osteoporotic vertebral body compression fractures of the lumbar and thoracic spine.

MATERIALS AND METHODS

Fifty-four symptomatic vertebral compression fractures in 30 patients with senile osteoporosis were treated with PPV by one physician (W.J.O.) over the course of 6 months. This practitioner was experienced in performing PPV and had already performed more than 100 such procedures before the initiation of this study. The study protocol was reviewed and approved by the Institutional Review Board at the medium-sized community hospital where all treatments were performed.

Patient Selection

All patients had demonstrated a less-than-satisfactory response to conventional therapy consisting of bed-rest and analgesics for at least 4 weeks. Plain radiographs or magnetic resonance images were evaluated in a preprocedural consultation; before therapy, the location of the patient's pain was correlated with physical examination under fluoroscopy. The amount of vertebral compression was determined by comparing the minimum height of the affected vertebral body on lateral radiographs to the expected normal height at that level, determined by substituting the vertical measurement of the closest adjacent normal vertebral body. The maximum degree of compression fracture treated was 75%. The average degree of compression was 50% (range, 25%–75%). Patients with loss of vertebral height greater than 75% or significant spinal stenosis (>25%) at the level of the fracture were not considered for treatment.

Patient Population

Our population consisted of three men and 27 women with a mean age of 79 years (range, 57–90 y). Fifty-four PPV procedures were performed for thoracic or lumbar compression fractures in these 30 patients. A single vertebral level was treated in 21 cases. Multiple levels were treated in 14 patients: eight patients had two levels treated, three patients had three levels

treated, two patients had four levels treated, and one patient had five levels treated. Two treatment sessions were necessary in seven patients, and three treatment sessions were required in two patients.

Technique

PPV was performed in a single-plane angiography suite (Multistar T.O.P.; Siemens, Erlangen, Germany) with intravenous sedation. The technique employed in all cases was essentially that described by Jensen et al (11) and Deramond et al (10), except with a different brand of PMMA (Surgical Simplex P; Howmedica, Rutherford, NJ). Also, in our series, alternating and nearly simultaneous injection through both pedicles was performed instead of treating the hemivertebrae in sequential fashion. A total of 4–8 mL of PMMA were injected into each treated vertebral body (Fig 1). The patients were allowed to recover for approximately 3 hours in the short-stay unit, during which time a limited computed tomographic (CT) scan was obtained through the treatment levels.

Pre- and Postprocedural Evaluation

The MODEMS Program offers 12 different questionnaires that have been thoroughly validated and tested to define quality of care for various musculoskeletal conditions (25–27). All questionnaires have a baseline and a follow-up version, and take approximately 15 minutes for the patient to complete. The spine questionnaire that we employed contains modules for evaluation of pain and disability, outcome satisfaction, mental function, and physical function.

The preoperative MODEMS questionnaire was administered to each patient within 4 hours before the procedure. Exactly 2 weeks after PPV, each patient responded to the follow-up questionnaire that was subsequently returned to us in a self-addressed, stamped envelope. Data were analyzed by Data Harbor, Inc. (Chicago, IL), an organization that maintains the MODEMS database for comparison among practices, and which also provided preliminary statistical analysis of our results. Responses to the four modules of the MODEMS spine questionnaire were then analyzed for sta-

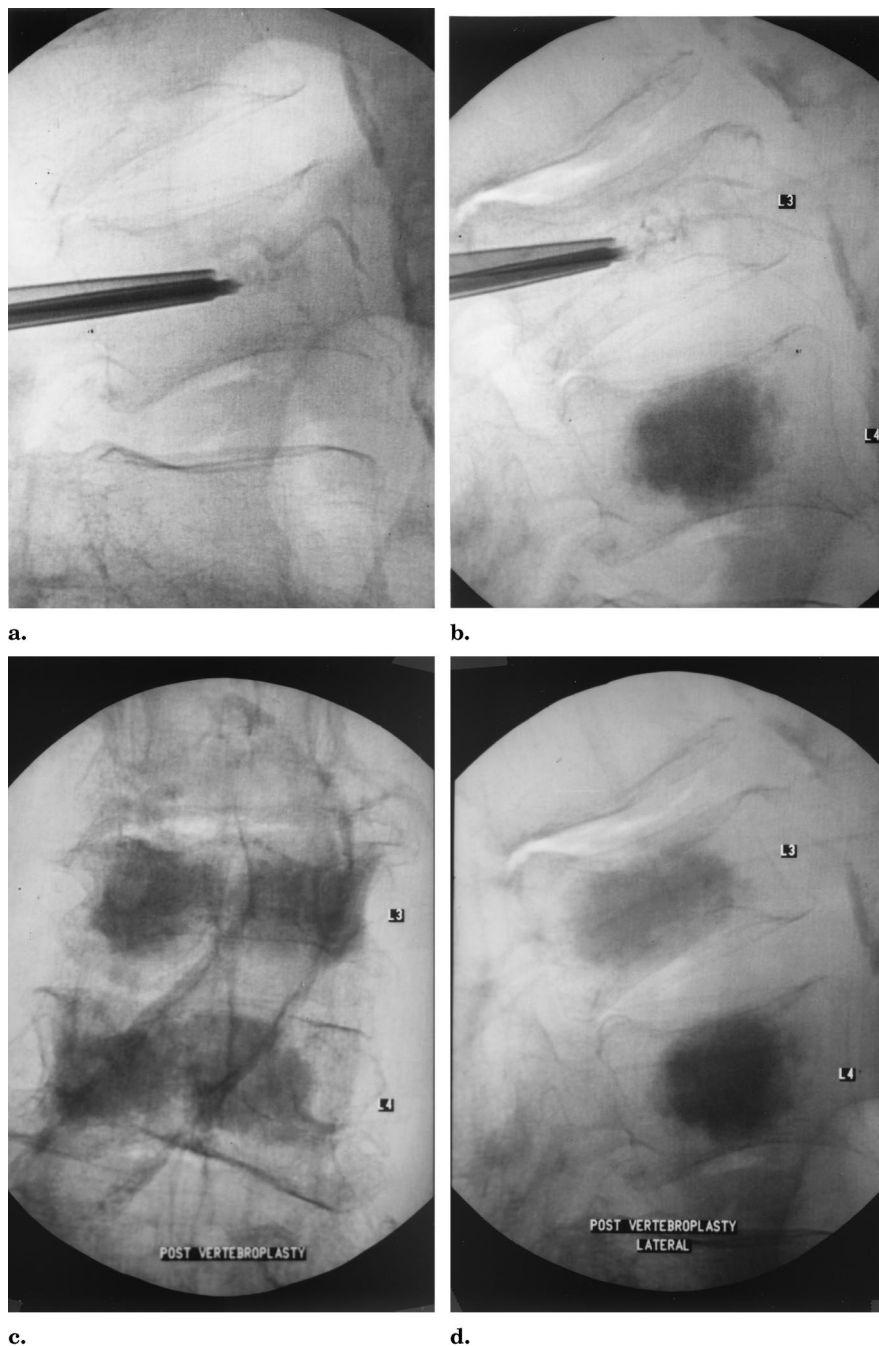


Figure 1. Multilevel vertebroplasty in a 79-year-old woman with osteoporotic L3 and L4 compression fractures: (a) Lateral radiograph demonstrating needle placement in the right and left L4 pedicles. (b) Lateral radiograph obtained after vertebroplasty at L4, with bone needles placed within the right and left L3 pedicles. (c) Anteroposterior and (d) lateral radiographs demonstrating PMMA bone cement within the L3 and L4 vertebral bodies after vertebroplasty. (*Fig 1 continues*)

tistically significant change with use of paired Student *t*-tests.

Module 1.—The treatment score was calculated before and after PPV. This score assesses the patients' ex-

pectations for treatment success before intervention. In the follow-up questionnaire, the patient is asked if the expectations for treatment were met and if they are satisfied with the

outcome. The patient is given the opportunity to state whether or not they would choose to undergo the same procedure again.

Module 2.—The pain and disability scores provide an indication of the limitations that are imposed on the patient before and after PPV and identifies where their pain is located. The patient is asked several questions concerning location of pain and how bothersome the pain has been during the previous week. They are also asked questions concerning their ability to perform certain tasks such as dressing themselves, lifting, sitting, walking, standing, sleeping, having sex, or traveling, and to rate how much their pain interferes with these activities. All of these questions are posed before and after PPV to determine if there is any change.

Modules 3 and 4.—The physical function and mental function scores represent portions of the SF-36 evaluation profile, which is included within the MODEMS instrument. The SF-36 is a comprehensive short-form questionnaire with 36 items that yields a health profile and summary measures of health-related quality of life (28–30).

A second follow-up questionnaire, including a verbal pain scale, was mailed to all patients between 15 and 18 months after their final vertebroplasty procedure to assess the durability of therapy. Patients were again asked whether the procedure had relieved the pain for which they were treated, if they were satisfied with the long-term outcome, and if they would have PPV performed again if they suffered another compression fracture in the future. Back pain before therapy, in the 2 weeks immediately after PPV, and at long-term follow-up was rated on a scale of 1–10. Patients were also asked whether they still took medication for back pain, and if they had experienced additional vertebral fractures. Patients who did not respond by mail were contacted by telephone and provided verbal responses when possible.

Study Endpoints and Adverse Events

It was our intention to follow all patients for a minimum of 1 year. Attempts at long-term follow-up were discontinued if three telephone calls



e.

Figure 1. (continued) (e) CT image demonstrating the deposition of PMMA within the L4 vertebral body. Note linear lucency in the right pedicle, corresponding to the track of the needle.

and three mailings of the follow-up questionnaire had resulted in no response.

Minor adverse events were defined as any unexpected or undesirable clinical occurrence within the 2 weeks after PPV, but which required no immediate or delayed surgical intervention. Serious adverse events were defined as any unexpected or undesirable clinical occurrence which required surgical intervention or which resulted in death or significant disability after PPV.

CT scans of each treated vertebral level were obtained within the first 3 hours after PPV. Axial images were acquired at 3-mm intervals beginning one level above and ending one level below the treated vertebrae. Images were reviewed independently by two neuroradiologists (W.J.O. and G.H.Z), and were assessed for unexpected or undesirable migration of cement, including significant filling of the epidural venous plexus, foraminal veins, or inferior vena cava.

Statistical Analysis

Data were analyzed by Data Harbor, Inc. (Chicago, IL), an organization that maintains the MODEMS database for comparison among practices, and which also provided preliminary statistical analysis of our results. Responses to the four modules of the MODEMS spine questionnaire were

then analyzed by one of the authors (J.R.H.) for significant change with use of paired Student *t*-tests. Verbal pain scale scores, including long-term follow-up, were analyzed with use of the Wilcoxon matched-pairs signed-rank test.

RESULTS

Early Results

Twenty-nine of 30 patients reported pain relief in the hours immediately after the procedure. There were two minor adverse events.

Posttreatment CT scans were obtained within 3 hours in all cases and were assessed for unexpected or undesirable migration of cement, including significant filling of the epidural venous plexus, foraminal veins, or inferior vena cava. A small epidural leak of PMMA (Fig 2) was asymptomatic and did not require intervention or treatment for this radiographic finding.

Another patient experienced a pulmonary embolism 6 days after PPV at a single level (L4). There was no extravertebral migration of PMMA in this patient, nor was there evidence of opacified PMMA on subsequent chest radiographs, and the pulmonary embolism was believed to be a result of fragmentation of lower extremity deep venous thrombosis related to previous prolonged inactivity. Although hospi-

talization was required, the patient recovered completely and uneventfully.

All patients completed and returned the 2-week follow-up questionnaire in a timely fashion. When asked how their current musculoskeletal condition compared to their pretreatment status, 24 of 30 patients (80%) reported feeling better. When asked if they could go back in time and make the decision again, 27 of 30 patients (90%) responded that they would still choose to have PPV performed.

Analysis of MODEMS data with use of paired *t*-tests confirmed significant improvement in all four modules 2 weeks after vertebroplasty (Table 1): treatment score ($P < .0001$), pain and disability ($P < .0001$), physical function ($P = .0004$), and mental function ($P = .0009$).

Late Results

The whereabouts or condition of all 30 patients was ascertained for follow-up, and long-term results were obtained by questionnaire between 15 and 18 months after the final vertebroplasty treatment. Three patients had died more than 6 months after vertebroplasty. One was in a rehabilitation facility and another was in a nursing home for terminal care. Two others were determined to be alive but did not respond to multiple mail and telephone inquiries. The remaining 23 of

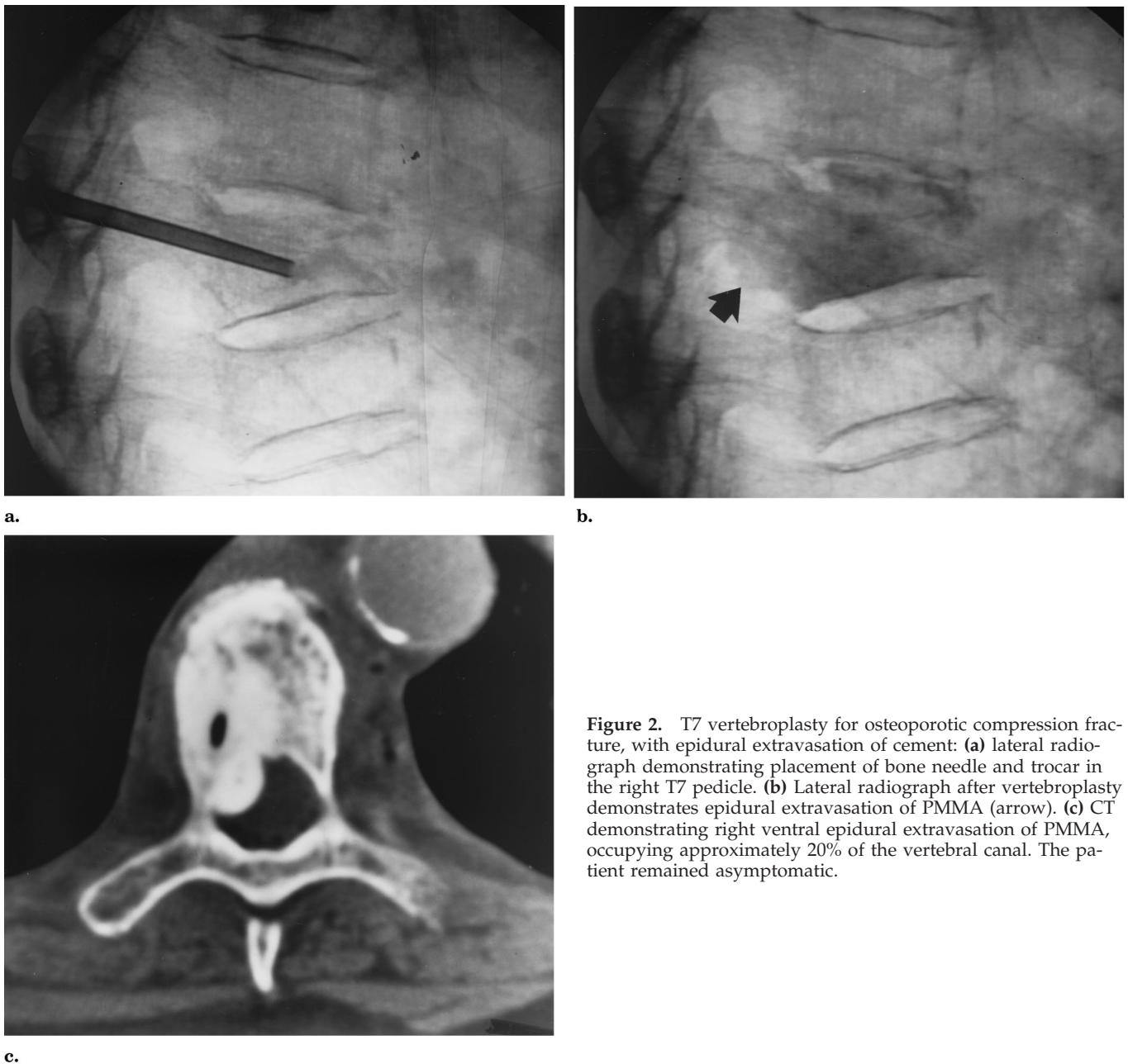


Figure 2. T7 vertebroplasty for osteoporotic compression fracture, with epidural extravasation of cement: (a) lateral radiograph demonstrating placement of bone needle and trocar in the right T7 pedicle. (b) Lateral radiograph after vertebroplasty demonstrates epidural extravasation of PMMA (arrow). (c) CT demonstrating right ventral epidural extravasation of PMMA, occupying approximately 20% of the vertebral canal. The patient remained asymptomatic.

30 patients responded to the follow-up questionnaire by mail or by providing answers via telephone. Twenty-two of 23 (96%) remained satisfied with the outcome and believed that the procedure continued to relieve the pain for which they were treated; 21 of 23 indicated that they would have PPV performed again if they experienced a future compression fracture. Fifteen of 23 patients still took some medication for back pain, and three of these 15 had experienced additional fractures

at untreated levels. Of these patients reporting back pain at the 15–18-month follow-up, the mean verbal pain rating was 3.89 out of 10 (range, 1–8). Three patients had undergone subsequent epidural steroid injections for back pain unrelated to vertebral compression fracture or PPV. Back pain before therapy was rated at a mean of 9.73 out of 10 (range, 5–10). In the 2 weeks immediately after vertebroplasty, pain was rated at a mean of 1.70 out of 10 (range, 0–6), and at long

term follow-up, 2.60 out of 10 (range, 0–8) for all 23 patients responding.

Verbal pain scale scores were analyzed with use of the Wilcoxon matched-pairs signed-rank test, a non-parametric equivalent to the paired *t*-test. Verbal pain scores documented significantly diminished back pain at 2 weeks ($P < .0001$) and at long-term follow-up when compared again to baseline ($P < .0001$). Comparison of long-term follow-up pain scores to verbal pain scores at 2 weeks showed

Raw Data and Results of Paired *t*-test Analyses, Demonstrating Significant Improvement in All Four MODEMS Modules at 2 Weeks after Final Vertebroplasty

	Pretreatment MODEMS Score	Posttreatment MODEMS Score	Paired <i>t</i> -test Analysis
Treatment expectations	75.36 ± 19.11	33.02 ± 26.97	<i>P</i> < .0001
Pain and disability	42.35 ± 18.01	61.47 ± 17.30	<i>P</i> < .0001
Physical function (SF-36)	23.21 ± 5.99	27.27 ± 6.92	<i>P</i> = .0004
Mental function (SF-36)	45.64 ± 12.85	50.54 ± 10.78	<i>P</i> = .0009

Note.—Values expressed as means ± SD where applicable.

no significant difference ($P = .4492$), demonstrating the durability of pain relief achieved by PPV.

DISCUSSION

Conventional treatment of vertebral fractures is typically nonoperative, and, until recently, has focused on the alleviation of acute pain with narcotic and nonsteroidal antiinflammatory agents. Pharmacologic intervention to improve bone marrow density has gained widespread acceptance in recent years (31). Because of significant risk caused by comorbid conditions that are common in this elderly patient population, as well as technical difficulty achieving adequate fixation of hardware within osteoporotic bone, surgical intervention is rarely undertaken (32). Pain and diminished mobility, loss of employment, and narcotic addiction are not the only potential sequelae of vertebral compression fractures. Patients may develop urinary retention, ileus, or spinal cord compression. Long-term effects can include kyphosis, insomnia, and depression (33). The actual cost related to this illness may therefore be underreported.

The fracture risk from osteoporosis increases with age in postmenopausal women. Men are also at risk for vertebral fractures, but partly because women live longer, the lifetime risk of a vertebral fracture from age 50 onward is 16% in white women and only 5% in white men. Fracture rates are lower outside of white populations (34).

Moderate or severe vertebral compression deformities have been found in 25% of 85-year-old white women (35). Although neurologic deficit caused by osteoporotic vertebral com-

pression fracture may be rare (36), vertebral compression fractures are nevertheless associated with significant impairment in functional, physical, and psychosocial indexes (37). Quality of life is impaired even after the first osteoporotic compression fracture and decreases further with additional fractures (5). Affected individuals have pain, disability, loss of activity, fear of falling, and embarrassment over their appearance (38). Skeletal deformity may progress even after extension bracing (39). Surgical intervention is rarely undertaken because of the inherent weakness of the osteoporotic bone (32). Excess mortality after an initial diagnosis of osteoporotic vertebral compression fracture increases progressively as the duration of follow-up increases (40).

Recent small series have demonstrated consistent and significant success with use of PPV to relieve the pain that results from osteoporotic vertebral compression fractures (11,13). Significant pain relief is achieved in 75%–90% of patients with benign fractures (10,11,13,23) and in 59%–86% of patients with malignant vertebral compression fractures (10, 12–14,41,42). PPV has also resulted in increased mobility and a diminished requirement for analgesics (11). Whether pain relief is caused primarily by structural reinforcement of the fractured vertebral body or by analgesia associated with a chemical or thermal effect of the methacrylate has not yet been determined; however, the occurrence of a repeated fracture at an adequately treated vertebral body level has not been reported and did not occur in our series.

Despite the increasing acceptance and clinical application of PPV since its initial description in the United

States in 1988 (8), we know of no controlled prospective studies on the safety or efficacy of PPV yet reported. Only one previous investigation has used an established outcome scale and questionnaire to prospectively measure the efficacy of PPV in patients with compression fractures (20). This study of 20 treatment levels in 16 patients used a visual analog scale, the McGill-Melzack scoring system (43), and the Nottingham Health Profile to assess patients at days 3, 30, 90, and 180 after treatment. Statistically significant improvements in assessment criteria were reported at all time points in all three scales.

Several recent studies have used visual analog or verbal pain scales to assess the efficacy of PPV. Both Deramond (10) and Martin (44) have reported complete relief of symptoms in patients who respond to treatment. However, in most reports, pain relief is substantial and significant but not complete (11,20,21,23,24). These results are consistent with our findings, which indicate a decrease in pain rating from 9.37 out of 10 before treatment to 1.70 out of 10 at 2 weeks after vertebroplasty. Patient satisfaction after PPV was high in our series (treatment score: $P < .0001$). Twenty-two of 23 patients (96%) responding were satisfied with the initial outcome at 2 weeks and believed that the procedure had continued to relieve the pain they were treated for; 21 of 23 (91%) indicated that they would have PPV performed again if they had another compression fracture.

Most previous studies of PPV have been retrospective and have reported only short-term results. Previous reports on the efficacy of PPV suggest that the treatment effect does not decrease over time. At a mean follow-up of 281 days, Jensen and Dion (22) reported durable benefit in 23 of 26 patients who initially experienced pain relief and increased mobility in the few days after treatment with PPV. When followed for an average of 18 months (21) and 6 months (23) after PPV, some patients developed new pain, but none reported a return of the pain for which they had initially sought treatment.

In another study, Grados et al (24) followed 25 patients for a mean of 48 months (range, 12–84 mo). Pain assessed by visual analog scale de-

creased significantly ($P < .05$) from a mean of 80 mm at baseline to 37 mm at 1 month and 34 mm at the time of maximum follow-up. Cortet et al (20) found significant improvement in pain with a trend of decreasing scores over time (days 3, 30, 90, and 180 after PPV) in five of six dimensions of the Nottingham Health Profile: pain ($P < .01$), physical mobility ($P < .05$), emotional reactions ($P < .05$), social isolation ($P < .05$), and energy ($P < .05$). We followed patients in our series for a minimum of 15 months after treatment and assessed the durability of PPV with a brief long-term follow-up questionnaire.

Our results in 22 of 23 patients responding 15–18 months after treatment reaffirm the durability of pain relief afforded by vertebroplasty in these earlier reports. Verbal pain scores documented significantly diminished back pain at 2 weeks ($P < .0001$) and at long-term follow-up when compared again to baseline ($P < .0001$). Long-term follow-up, performed 15–18 months after treatment, documented continued satisfaction with treatment results in 22 of 23 patients responding. Comparison of long-term follow-up pain scores to the verbal pain scores at 2 weeks showed no statistically significant difference ($P = .4492$), demonstrating the durability of pain relief achieved by PPV.

An increased incidence of vertebral fractures has been documented in patients with diminished bone mass and preexisting vertebral fractures. Differences of 2 standard deviations in bone mass between groups were associated with an increase in risk of new fractures of as much as 16 fold. The presence of a single vertebral fracture at baseline examination was associated with a five-fold increase in risk, whereas the presence of two or more fractures at baseline increased the risk of new vertebral fracture by 12 times. Women with both low bone mass and two preexisting fractures at baseline were as much as 75 times more likely to develop new fractures when compared to the lowest risk groups (45). During their mean follow-up of 281 days in 26 patients, Jensen and Dion (22) reported that seven of eight patients who experienced recurrent back pain were discovered to have new vertebral fractures at untreated levels; the eighth patient had refractured a previ-

ously treated but inadequately filled vertebral body. In another series, five of 20 patients had pain related to new vertebral collapse at untreated levels (23). Grados et al (24) reported at least one new fracture in 13 of 25 patients (52%), and 34 new fractures in total, when their patients were followed for a mean of 48 months; the odds ratio for a new vertebral fracture in the vicinity of a treated vertebral body was 2.27 (95% CI: 1.11–4.56) compared to 1.44 (95% CI: 0.82–2.55) for new fractures in the vicinity of an untreated vertebral fracture. Whether PPV truly increases the risk of compression fracture adjacent to treated vertebrae remains to be determined and is a topic for study in larger series. There were no new fractures in any of our patients within the first 2 weeks after PPV. Fifteen of 23 patients responding to long-term follow-up in our study reported some degree of back pain; three patients had experienced new vertebral fractures at untreated levels.

MODEMS, the Musculoskeletal Outcomes Data Evaluation and Management System, is the outcomes program of the American Academy of Orthopedic Surgeons. MODEMS was developed in 1995 in conjunction with the Council of Musculoskeletal Specialty Societies and the Council of Spine Societies, and was initially conceived as a large-scale practice database. Although the database currently lacks funding for continued patient enrollment, the questionnaires have been thoroughly tested for validity, reliability, and sensitivity, and “perform as well as or better than the SF-36 in describing and classifying patients with musculoskeletal complaints” (25). The MODEMS questionnaires have been used as a basis for assessing pain, function, and patient satisfaction in adults undergoing spinal surgery (26), and have been used to compare long-term results in patients undergoing spine surgery versus bracing (27). As such, this outcome measure is ideally suited to evaluate the efficacy of musculoskeletal interventions such as PPV. MODEMS was designed for comparison of a specific clinical population against a large, national outcomes database, or to track the outcomes of a specific population within a single clinic or practice such as our series of patients undergoing PPV.

In evaluating our patients’ re-

sponses to the MODEMS questionnaire, we analyzed the results of four specific modules: pain and disability, treatment expectations and satisfaction, mental function, and physical function. Responses to the MODEMS spine questionnaire were analyzed with use of a paired *t*-test. There was clear significant improvement in all four modules. The latter two modules are components of the SF-36, a well-established and validated health status survey. The entire SF-36 is contained within the MODEMS spine questionnaire. As documented in more than 750 publications, the SF-36 has been proven useful in monitoring general and specific populations, comparing the burden of different diseases, differentiating the health benefits produced by different treatments, and in screening individual patients. The reliability of the SF-36 has been estimated with use of both internal consistency and test-re-test methods. With rare exceptions, published reliability statistics have exceeded the minimum standard of 0.70 recommended for measures used in group comparisons; most have exceeded 0.80. Reliability estimates for physical and mental summary scores usually exceed 0.90 (28–30). The SF-36 has been specifically recommended for the evaluation of patients with back pain (46,47) or undergoing spine surgery (48,49), and has been used previously to study quality of life and functional impairment in women with osteoporotic vertebral fractures (50). The SF-36 has also recently been used to study the outcomes of another new percutaneous spine treatment for discogenic low back pain (51), as well as the outcomes in patients undergoing lumbar disc surgery (52) and lumbar spinal fusion (53).

The advanced age of our cohort (mean, 79 y) predisposed our patients to multiple medical problems, and in some cases, terminal intercurrent illnesses. Determining the whereabouts and health status of these 30 patients required diligence and persistence. Ultimately, all patients were accounted for, and 23 were able to provide reliable answers that reflected durable efficacy of vertebroplasty in relieving pain from vertebral compression fractures. Difficulties that we encountered in following elderly patients for long-term follow-up will likely affect any

study of PPV for senile osteoporosis. Of the 40 patients treated by Grados et al (24) between January 1990 and April 1996, 15 were unavailable for follow-up in 1997; at least 10 had died from cardiovascular causes 6 months or more after PPV. In fact, the high mortality rate and incidence of concurrent illness in such an elderly cohort of patients suggests that future analyses of the efficacy of PPV should continue to focus on quality of life in the short and intermediate term, perhaps within the first 12 months after treatment, rather than several years later.

The excellent results obtained in our patients, and the lack of serious complications, may be partially attributed to the fact that all cases were performed by a single experienced operator. PPV should only be performed by physicians who have been allowed to observe the procedure and who have had the opportunity to train with another experienced operator. The ability to perform the procedure on cadavers before clinical application may be of significant additional benefit.

We believe that careful patient selection is essential to the success of PPV. All our patients were seen in consultation before the procedure. Many patients with osteoporosis will have multiple vertebral body compression deformities, not all of which require treatment with PPV. An examination under fluoroscopy is helpful to ascertain that the painful vertebral body can be localized and identified. In a substantial portion of our cases, treatment at multiple levels was indicated (14 of 30 patients; 47%) and was performed in single or multiple treatment sessions. At all treated levels, careful physical examination under fluoroscopy confirmed the clinical relevance of a radiographic vertebral compression deformity.

Intraosseous venography was performed in all cases before instillation of PMMA to predict the flow of cement; the utmost attention was given to detect migration of contrast material or PMMA beyond the confines of the vertebral body during injection. With significant additional experience, we no longer perform venography as part of our standard routine, but reserve its use for selected cases such as those with fracture of the posterior vertebral cortex.

Previously reported complications of the procedure have included epidural or foraminal extravasation of PMMA (12,14); however, the need for subsequent surgical intervention is rare (12). There was no clinically significant epidural or foraminal extravasation in any of our patients, all of whom had a limited CT scan of the operative level performed within 3 hours after PPV. Radiographic (CT) evidence of epidural extravasation in one patient was mild and was not accompanied by immediate or delayed complaints suggesting neurologic deficit. No intervention was required. Discitis, osteomyelitis, or epidural infection did not occur in any of our patients. One patient who experienced a small pulmonary embolism 6 days after PPV required hospitalization, but had a good clinical recovery. There was no evidence at the time of the procedure or on subsequent chest radiographs to suggest that there had been pulmonary embolization of opacified PMMA. We believe that the restoration of mobility after PPV in this patient may have dislodged fragments of lower extremity deep venous thrombosis that could have formed during the several weeks of bedrest preceding our intervention. This suggests that physicians performing PPV should be familiar with the signs of deep venous thrombosis, and careful examination should be performed at the time of intervention.

A variety of needle trajectories may be chosen to access the fractured vertebral body. Safe needle placement under fluoroscopy must avoid not only the spinal canal and exiting nerve roots, but also the center of the posterior portion of the vertebral body, where there may be a higher likelihood of entering a large channel of the basivertebral plexus (Fig 3). For that reason, we favor a transpedicular approach, when possible, over a posterolateral approach to avoid the central venous plexus. We perform the procedure in a dedicated imaging suite; we believe that portable fluoroscopic equipment most often used in the operating room typically produces live images that are inferior in quality compared to stationary C-arm equipment. This, in addition to overlying bowel gas and other visceral structures, may hamper the visual detec-

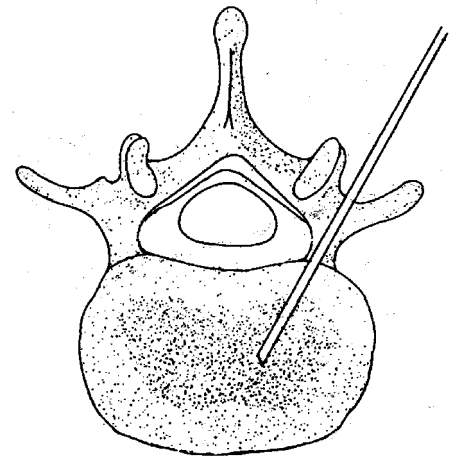


Figure 3. Transaxial schematic drawing demonstrates the trajectory and position of an 11-gauge bone marrow needle for PPV. The needle courses along the long axis of the pedicle, parallel to the surrounding cortices. On the lateral view, the needle tip should be positioned at the junction of the anterior and middle thirds of the vertebral body. In the frontal projection, the tip should lie within the lateral third of the vertebra. The central portions of the vertebral body should be avoided to minimize the chance of epidural PMMA migration that can occur with injection directly into the basivertebral plexus.

tion of PMMA extravasation in the operating room setting.

The same technique used for PPV may be adapted to the delivery of other osteoconductive or osteoinductive materials such as hydroxyapatite, collagen, tricalcium phosphate, or bone morphogenetic proteins. In addition, several companies are working to develop other structural cements with increased opacification and compressive strength compared to PMMA. Protocols for clinical trials of some of these agents are currently in preparation.

In experienced hands and with appropriately selected patients, PPV is a safe and efficacious procedure for the treatment of pain and disability associated with osteoporotic compression fractures. Patient satisfaction is high. This prospective study with long-term follow-up is the first to use a recognized outcome scale designed specifically by orthopedic surgeons to assess the results of surgical spine interventions. The results of follow-up after 15–18 months demonstrate the dura-

bility of pain relief provided by PPV. The excellent outcomes and low incidence of complications suggest that PPV may even be considered early in the acute phase for treatment of vertebral compression fractures in patients who are at increased risk of thrombophlebitis, pneumonia, or decubitus ulcer, or who face other urgent needs to return to full mobility as quickly as possible. Further investigation is required to determine whether vertebrae adjacent to levels treated with PPV are truly at increased risk for subsequent fracture.

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References

- Glaser DL, Kaplan FS. Osteoporosis: Definition and clinical presentation. *Spine* 1997; 22(24S):12S-16S.
- World Health Organization. Assessment of fracture risk and its application to screen for postmenopausal osteoporosis. Report of a World Health Organization Study Group. *World Health Organ Tech Rep Ser* 1994; 843: 1-129.
- Iqbal MM. Osteoporosis: epidemiology, diagnosis, and treatment. *South Med J* 2000; 93:2-18.
- Melton LJ, Chrischilles EA, Cooper C, Lane AW, Riggs BL. Perspective: how many women have osteoporosis? *J Bone Miner Res* 1992; 7:1005-1010.
- Kanis JA, Johnell O. The burden of osteoporosis. *J Endocrinol Invest* 1999; 22:583-588.
- Eastell R, Cedel SL, Wahner HW, Riggs BL, Melton LJ. Classification of vertebral fractures. *J Bone Miner Res* 1991; 6:207-215.
- O'Neill TW, Silman AJ. Definition and diagnosis of vertebral fracture. *J Rheumatol* 1997; 24:1208-1211.
- Bascoulergue Y, Duquesnel J, Leclercq R, Mottolese C, Lapras C. Percutaneous injection of methyl methacrylate in the vertebral body for treatment of various diseases: percutaneous vertebroplasty. *Radiology* 1988; 169(P):372.
- Deramond H, Galibert P, Debussche C. Vertebroplasty. *Neuroradiology* 1991; 33S:177-178S.
- Deramond H, Depriester C, Galibert P, Le Gars D. Percutaneous vertebroplasty with polymethylmethacrylate: technique, indications and results. *Radiol Clin North Am* 1998; 36:533-546.
- Jensen ME, Evans AJ, Mathis JM, Kallmes DF, Cloft HJ, Dion JE. Percutaneous polymethylmethacrylate vertebroplasty in the treatment of osteoporotic vertebral body compression fractures: technical aspects. *Am J Neuroradiology* 1997; 18:1897-1904.
- Cotten A, Dewatre F, Cortet B, et al. Percutaneous vertebroplasty for osteolytic metastases and myeloma: effects of the percentage of lesion filling and the leakage of methyl methacrylate at clinical follow-up. *Radiology* 1996; 200: 525-530.
- Gangi A, Kastler BA, Dietman JL. Percutaneous vertebroplasty guided by a combination of CT and fluoroscopy. *Am J Neuroradiol* 1994; 15:83-86.
- Weill A, Chiras J, Simon JM, Rose M, Sola-Martinez T, Enkaoua E. Spinal metastases: indications for and results of percutaneous injection of acrylic surgical cement. *Radiology* 1996; 199:241-247.
- Cotten A, Deramond H, Cortet B, et al. Preoperative percutaneous injection of methyl methacrylate and N-butyl cyanoacrylate in vertebral hemangiomas. *Am J Neuroradiol* 1996; 17:137-142.
- Dousset V, Moussellard H, de Monck d'User L, et al. Asymptomatic cervical haemangioma treated by percutaneous vertebroplasty. *Neuroradiology* 1996; 38:392-394.
- Feydy A, Cognard C, Miaux Y, et al. Acrylic vertebroplasty in symptomatic cervical vertebral haemangiomas: report of 2 cases. *Neuroradiology* 1996; 38:389-391.
- Ide C, Gangi A, Rimmelin A, et al. Vertebral haemangiomas with spinal cord compression: the place of preoperative percutaneous vertebroplasty with methyl methacrylate. *Neuroradiology* 1996; 38:585-589.
- Mathis JM, Petri M, Naff N. Percutaneous vertebroplasty treatment of steroid-induced osteoporotic compression fractures. *Arthritis Rheum* 1998; 41:171-175.
- Cortet B, Cotten A, Boutry N, et al. Percutaneous vertebroplasty in the treatment of osteoporotic vertebral compression fractures: an open prospective study. *J Rheumatol* 1999; 26: 2222-2228.
- Barr JD, Barr MS, Lemley TJ, McCann RM. Percutaneous vertebroplasty for pain relief and spinal stabilization. *Spine* 2000; 25:923-928.
- Jensen ME, Dion JE. Vertebroplasty relieves osteoporosis pain. *Diagn Imaging* 1997; 19:68,71-72.
- Cyvetal C, Sarrabere MP, Roux JO, et al. Acute osteoporotic vertebral collapse: open study on percutaneous injection of acrylic surgical cement in 20 patients. *AJR Am J Roentgenol* 1999; 173:1685-1690.
- Grados F, Depreister C, Cayrolle G, Hardy N, Deramond H, Fardellone P. Long term observations of vertebral osteoporotic fractures treated by percutaneous vertebroplasty. *Rheumatology* 2000; 39:1410-1414.
- Musculoskeletal Outcomes Data Evaluation and Management System (MODEMS) User's guide. Chicago: Data Harbor, January 1999.
- Lapp MA, Bridwell KH, Lenke LG, et al. Long-term complications in adult spinal deformity patients having combined surgery: a comparison of primary to revision patients. *Spine* 2001; 26:973-998.
- Danielsson AJ, Wiklund I, Pehrsson, Nachemson AL. Health-related quality of life in patients with adolescent idiopathic scoliosis: a matched follow-up at least 20 years after treatment with brace or surgery. *Eur Spine J* 2001; 10:278-288.
- Ware JE, Sherbourne CD. The MOS 36-Item Short-Form Health Survey (SF-36): I. Conceptual framework and item selection. *Med Care* 1992; 30:473-483.
- Ware JE. The SF-36 Health Survey. The Health Institute, New England Medical Center; December 1998. Available online at <http://www.sf36.com/general/sf36.html>.
- Ware JE Jr. SF-36 health survey update. *Spine* 2000; 25:3130-3139.
- O'Connell MB. Prevention and treatment of osteoporosis in the elderly. *Pharmacotherapy* 1999; 19:7S-20S.
- National Institutes of Health. Osteoporosis prevention, diagnosis, and therapy. NIH Consensus Statement 2000; 17:1-36.
- Bostrom MP, Lane JM. Future directions: augmentation of osteoporotic vertebral bodies. *Spine* 1997; 22(24S): 38S-42S.
- Melton, LJ. Epidemiology of spinal osteoporosis. *Spine* 1997; 22(24S):2S-11S.
- Johansson C, Melstrom D, Rosengren K, Rundgren A. Prevalence of vertebral fractures in 85-year-olds: radiographic examination of 462 subjects. *Acta Orthop Scand* 1993; 64:25-27.
- Heggeness MH. Spine fracture with neurological deficit in osteoporosis. *Osteoporos Int* 1993; 3:215-221.
- Lyles KW, Gold DT, Shipp KM, Pieper CF, Martinez S, Mulhausen PL. Association of osteoporotic vertebral compression fractures with impaired functional status. *Am J Med* 1993; 94:595-601.

38. Ross PD, Ettinger B, Davis JW, Melton LJ, Wasnich RD. Evaluation of adverse health outcomes associated with vertebral fractures. *Osteoporosis Int* 1991; 1:134-140.
39. Karjalainen M, Aho AJ, Katevuo K. Painful spine after stable fractures of the thoracic and lumbar spine—what benefit from the use of extension brace? *Ann Chir Gynaecol* 1991; 80:45-48.
40. Cooper C, Atkinson EJ, Jacobsen SJ, O'Fallon WM, Melton LJ. Population-based study of survival after osteoporotic fractures. *Am J Epidemiol* 1993; 137:1001-1005.
41. Cortet B, Cotten A, Boutry N, et al. Percutaneous vertebroplasty in patients with osteolytic metastases or multiple myeloma. *Rev Rheum Engl Ed* 1997; 64:177-183.
42. Kaemmerlen P, Thiesse P, Jonas P, Duquesnel J, Bascoulergue, Lapras C. Percutaneous injection of orthopaedic cement in metastatic vertebral lesion [letter] *N Engl J Med* 1989; 321:121.
43. Melzack R. The McGill Pain Questionnaire: major properties and scoring methods. *Pain* 1975; 1:275-279.
44. Martin JB, Jean B, Sugiu K, et al. Vertebroplasty: clinical experience and follow-up results. *Bone* 1999; 25(2S):11S-15S.
45. Ross PD, Davis JW, Epstein RS, Wasnich RD. Pre-existing fractures and bone mass predict vertebral fracture incidence in women. *Ann Intern Med* 1991; 114:919-923.
46. Bombardier C. Outcomes assessment in the evaluation of treatment of spinal disorders: summary and general recommendations. *Spine* 2000; 25:3100-3103.
47. Fanuele JC, Birkmeyer NJ, Abdu WA, Tosteson TD, Weinstein JN. The impact of spinal problems on the health status of patients: have we underestimated the effect? *Spine* 2000; 25:1509-1514.
48. Grevitt M, Khazim R, Webb J, Mulholland R, Shepperd J. The short form-36 health survey questionnaire in spine surgery. *J Bone Joint Surg Br* 1997; 79: 48-52.
49. Glassman SD, Minkow RE, Dimar JR, Puno RM, Raque GH, Johnson JR. Effect of prior lumbar discectomy on outcome of lumbar fusion: a prospective analysis using the SF-36 measure. *J Spinal Disord* 1998; 11:383-388.
50. Hall SE, Criddle RA, Comito TL, Prince RL. A case-control study of quality of life and functional impairment in women with long-standing vertebral osteoporotic fracture. *Osteoporosis Int* 1999; 9:508-515.
51. Saal JA, Saal JS. Intradiscal electrothermal treatment for chronic discogenic low back pain: a prospective outcome study with minimum 1-year follow-up. *Spine* 2000; 25:2622-2627.
52. Hutchinson PJ, Laing RJ, Waran V, Hutchinson E, Hollingworth W. Assessing outcome in lumbar disc surgery using patient completed measures. *Br J Neurosurg* 2000; 14:195-199.
53. Glassman SD, Dimar JR, Johnson JR, Minkow R. Preoperative SF-36 responses as a predictor of reoperation following lumbar fusion. *Orthopedics* 1998; 21:1201-1203.