Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 14: brace therapy as an adjunct to or substitute for lumbar fusion

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**Key Words** • lumbar spine • fusion • orthotic device • brace therapy • practice guidelines

**Recommendations**

**Standards.** There is insufficient evidence to recommend a treatment standard.

**Guidelines.** The short-term use of a rigid lumbar support (1–3 weeks) is recommended as a treatment for low-back pain of relatively short duration (< 6 months). The use of a lumbar brace for patients with chronic low-back pain is not recommended because there is no pertinent medical evidence of any long-term benefit or evidence that brace therapy is effective in the treatment of patients with chronic (> 6 months) low-back pain.

**Options.** 1) Lumbar braces are recommended as a means of decreasing the number of sick days lost due to low-back pain among workers with a previous lumbar injury. They are not recommended as a means of decreasing low-back pain in the general working population. 2) The use of lumbar brace therapy as a preoperative diagnostic tool to predict outcome following lumbar fusion surgery is not recommended. 3) The use of transpedicular external fixation as a tool to predict outcome following lumbar fusion surgery is not recommended.

**Rationale**

Lumbosacral supports or back braces have been used for the prevention and treatment of a wide variety of degenerative disorders of the lumbar spine. The potential mechanisms of action for brace therapy include limiting spinal ROM, correcting posture and deformity, preventing gross trunk motion, increasing the intraabdominal pressure, reducing force exerted by trunk muscles, and providing soft-tissue massage and heat. Critics of lumbar supports have argued that braces may provide workers with a false sense of support or allow muscles to waste, thereby increasing the incidence of injury. Although the mechanism of action of lumbar supports remains open to debate, their clinical utility in the prevention and treatment of low-back pain must be determined to justify their use.

Braces have been used for the preoperative evaluation of patients in an attempt to predict outcome following fusion surgery. They are also applied following lumbar surgery to promote fusion. Because lumbar orthoses do not eliminate motion in the lumbar spine, their utility has been questioned. The purpose of this review is to exam-
Brace therapy in lumbar degenerative disease

ine the medical evidence for the utility of brace therapy as a treatment of low-back pain, as a predictor of outcome following lumbar fusion surgery, and as an adjunct to lumbar fusion procedures.

**Search Criteria**

A computerized search of the National Library of Medicine from 1966 to 2003 was conducted using the following search terms: “lumbar support and low-back pain,” “brace and low-back pain,” and “orthosis and low-back pain.” After discarding duplicates, 760 papers were identified. After reviewing the abstracts of each paper, 17 relevant studies were identified. We then searched the database using the following phrases: “orthosis and fusion,” “brace and fusion,” “external lumbar fixation and fusion,” and “lumbar support and fusion.” After discarding duplicates, 1951 papers were identified. After reviewing the abstracts of each paper, 12 relevant studies were identified. Several review papers, metaanalyses, biomechanical studies, technical notes, and small case series serve as supporting data. The bibliography of each paper was reviewed and other relevant studies were identified. All clinical studies providing Class III medical evidence or better regarding the use of lumbar brace therapy for the prevention and treatment of low-back pain, for the prediction of outcome following lumbar fusion surgery, and as an adjunct to fusion surgery are summarized in Tables 1 through 4.

**Scientific Foundation**

Lumbar braces have been used as a means of preventing low-back pain in industrial workers. Van Poppel, et al., randomized 282 individuals employed as baggage handlers into one of four groups: 1) education and lumbar brace; 2) education; 3) lumbar brace; and 4) no intervention. Soft lumbar braces were worn during working hours for a 6-month period by workers randomized to Groups 1 and 3. There was no decrease in the incidence of reported back pain (36% for braced individuals and 34% for non-braced) or in the number of sick days lost when comparing braced with nonbraced workers; however, a subgroup analysis of workers with prior back pain revealed that the use of a soft lumbar brace reduced the number of days lost due to back pain from 6.5 to 1.2 days per month (p = 0.03). It should be noted that only 43% of the workers complied with the bracing protocol. There was no difference in the incidence of low-back pain or number of sick days lost between compliers and noncompliers in the brace-treated group. The authors concluded that brace therapy does not diminish the incidence of low-back pain or time lost from work when used as a preventive strategy. The use of a lumbar support by workers with a previous low-back injury may result in fewer days lost due to low-back pain. Because of the high number of noncompliant workers, this study is considered to provide Class III medical evidence.

Reddell and colleagues randomized 642 individuals employed as baggage handlers into one of four groups: 1) education; 2) weight belt–type brace; 3) education and brace; and 4) no intervention. During an 8-month period, the authors examined the total incidence of reported low-back injury, lost or restricted workdays due to low-back pain, and Workers’ Compensation claims related to low-back pain. They found no differences among the groups with respect to these outcome measures. Similar to the van Poppel study, only 42% of the brace-treated group was compliant with the use of the brace. The noncompliant group (158 individuals) was followed and found to have a higher incidence of lost work days, but the difference between the compliant and noncompliant groups was not significant. This study also provides Class III medical evidence suggesting no benefit for the use of a lumbar orthosis to prevent back injury. Alexander, et al., reported the results of a prospective study of 60 healthcare workers divided into two groups. One group was assigned to use a beltlike corset for a 3-month period. No differences in work-related back injuries or perception of back pain were noted. Because a nonvalidated outcome measure was used, this paper also provides Class III evidence suggesting that brace therapy involving a corset-type orthosis is not an effective measure to prevent low-back pain.

Walsh and Schwartz randomly selected 90 individuals from a pool of 800 warehouse workers and assigned them into one of three groups: 1) no intervention; 2) 1-hour education; or 3) 6-month lumbosacral molded semi-rigid orthosis therapy and education. Outcomes were assessed using various measures including work injury incidence, work productivity, and utilization of healthcare resources. Brace-treated workers missed 2.5 days less work (p = 0.03) than those not wearing braces (both controls and education-only groups), but there were no differences in productivity or utilization of healthcare resources between the groups. A subgroup analysis revealed that the benefit in terms of number of lost work days was greatest in patients with a previous back injury. The authors concluded that the combination of brace therapy and education was effective in reducing time lost to injury, especially among patients with a history of back injury. Because there was no information given regarding worker compliance with the bracing routine, the medical evidence offered in this report in support of brace therapy as a measure to prevent low-back pain is considered Class III.

Several historical cohort studies have examined the incidence of back pain and days lost to work in groups of workers before and after being issued a brace or lumbar support belt by their employer. Analysis of these studies revealed mixed results. One study identified no change in the incidence of back pain and sick days after application of the brace and two studies reported a reduction in these parameters following the issue of a lumbar support to employees. Overall, the medical evidence supporting the use of braces as a preventive measure for low-back pain is inconsistent. The authors of several systematic literature reviews have concluded that lumbar support devices are not useful for the prevention of low-back pain in the general working population. It does appear, however, that braces may be useful as a measure to decrease the number of sick days lost due to low-back pain in workers with a history of low-back injury.

In several randomized control trials the role of bracing as a treatment for low-back pain has been examined. Pope, et al., studied 164 patients with low-back pain drawn from a chiropractic clinic. Patients were randomized to one of four treatments: 1) chiropractic manipulation; 2) TMS; 3) massage; and 4) lumbar corset. Patients were assessed for pain...
### TABLE 1

Summary of studies involving the use of preventative brace therapy

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<th>Authors &amp; Year</th>
<th>Class</th>
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<tr>
<td>Walsh &amp; Schwartz, 1990</td>
<td>II</td>
<td>90 individuals randomly selected from 800 warehouse workers. 3 groups w/o intervention, 1 hr of education, or 6 mos of LSO + education. Outcome assessed as 1) abdominal strength; 2) educational assessment; 3) work injury incidence; 4) productivity; &amp; 5) use of healthcare resources. &gt;90% FU. No information on brace compliance or subject selection.</td>
<td>Workers in Group 3 missed 2.5 days less work in the 6-mo trial. No differences in productivity. High-risk individuals (those w/ previous back complaints) had a greater effect, w/ 5.9 fewer lost work days in Group 3 &amp; 2 in Group 2. Authors recommended that back braces not be routinely used for the prevention of LBI in this population. Dropout group had higher incidence of injury than control or education groups (data not included). Even though no benefit demonstrated, almost 70% of the participants found a brace helpful.</td>
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<tr>
<td>Reddell, et al., 1992</td>
<td>II</td>
<td>642 baggage handlers randomized to 1 of 4 groups: 1) education; 2) bracing; 3) education + bracing; &amp; 4) nothing. 58% of group had previous LBI &amp; 26% had a specific LBI. Looked at total incidence of injury, lost or restricted workdays, &amp; Workers' Compensation rates over 8-mo period. Found no differences among groups w/ respect to these outcomes. Compliance rate was only 42%.</td>
<td>Authors concluded that lumbar supports were effective in reducing the incidence of back injury in this population of workers.</td>
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<tr>
<td>Thompson, et al., 1994</td>
<td>II</td>
<td>The primary aim of the study was a prospective study of 60 healthcare transport workers who were divided into 2 groups w/ 41 braced (+ back school intervention) &amp; 19 nonbraced for 3 mos. Attitudes improved w/ belt availability &amp; frequency of back pain decreased in the belted group.</td>
<td>Lumbar supports do not reduce LBP incidence or sick leave when used as a preventative strategy for LBP. Unlike previous studies there was no increase in the incidence of LBP in the groups discontinuing use of the belt.</td>
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<tr>
<td>Alexander, et al., 1995</td>
<td>II</td>
<td>60 healthcare workers were divided into 2 groups, 30 w/ corset who wore brace during work for 3 mos. No differences in work-related back injuries or subjective perception of back pain; however, 70% of the corset group felt that the belt aided in avoiding injury &amp; 29 of 30 said the belt made them &quot;feel good.&quot;</td>
<td>No mention of compliance w/ the bracing. Does the brace make the employee feel &quot;overconfident?&quot; No benefit of bracing.</td>
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<tr>
<td>Kraus, et al., 1996</td>
<td>II</td>
<td>Historical cohort study examining incidence of LBP in workers at 1 company prior to institution of a back-support-use policy &amp; after that policy was instituted. 36,000 employees participated. After the policy was instituted, there was a 34% reduction in rate of LBP/million hrs worked. This effect was noted in both sexes, across all age groups &amp; throughout all types of jobs.</td>
<td>No benefit of bracing. Authors concluded that lumbar supports were effective in reducing the incidence of back injury in this population of workers.</td>
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<tr>
<td>van Poppel, et al., 1998</td>
<td>II</td>
<td>282 (of 312) Dutch baggage handlers randomized into 1 of 4 groups: 1) education &amp; lumbar support; 2) education; 3) lumbar support; &amp; 4) no intervention. Lumbar supports used during work hours for a 6-mo period. Only a 43% compliance rate w/ soft brace. No decrease (36 vs 34%) in incidence of back pain in groups w/ or w/o bracing. No decrease in sick leave. In 1 subgroup of patients (those w/ previous back pain) bracing reduced days lost to back pain from 6.5 to 1.2.</td>
<td>Lumbar supports do not reduce LBP incidence or sick leave when used as a preventative strategy for LBP. Unlike previous studies there was no increase in the incidence of LBP in the groups discontinuing use of the belt.</td>
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* FU = follow up; LBI = low-back injury; LBP = low-back pain; LSO = lumbosacral orthosis.
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<td>Coxhead, et al., 1981</td>
<td>II</td>
<td>322 patients randomized to traction, exercises, manipulation, &amp; corset. Patients had sciatic pain w/ or w/o back pain. Factorial study design so that 16 groups were present in total. Treatment lasted for 4 wks &amp; outcome was assessed at 1, 4, &amp; 16 mos. Outcome measures at 1 mo were improvement on VAS. At all time points patients given a better, same, worse satisfaction questionnaire. Also RTWS assessed at 1 &amp; 4 mos. 91% FU at 1 mo &amp; 80% at 16 mos. Patients receiving manipulation had more VAS improvement at 4 wks. There is a trend toward more subjective improvement in patients receiving more treatments.</td>
<td>No significant differences in any group at 4 &amp; 16 mos. Manipulation patients had greater improvement in pain. Active physiotherapy useful in the short term.</td>
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<td>Million, et al., 1981</td>
<td>II</td>
<td>19 patients w/ chronic LBP were randomized to receive either a soft corset or a corset w/ an inset. Subjective &amp; objective outcomes were compared at 4 &amp; 8 wks. The subjective was a 15-item questionnaire that looked at pain &amp; limitation in function as answered by a VAS (Million Scale). The objective measurements were ROM &amp; SLR. There were no intergroup differences w/ regard to objective criteria, but there was an improvement in pain &amp; function as assessed by the Million Scale.</td>
<td>Authors concluded that the benefit of a lumbar support does not occur based on increase in intraabdominal pressure as evidenced by the lack of improvement in the group w/ the soft binder. The study has a small sample size &amp; short period of use for the brace. Only control group given a soft binder.</td>
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<td>Willner, 1985</td>
<td>III</td>
<td>48 patients w/ LBP from 3 conditions. Patients returned at a mean of 1 yr &amp; were asked if symptoms were unchanged, improved, or resolved. Patients w/ spondylo fared the best w/ 13/15 experiencing complete relief &amp; the other two significant improvement in the pain. Spinal stenosis patients had 2/7 w/ complete relief &amp; 4/7 w/ some relief. In cases of LBP of unknown origin 17/26 had no relief of back pain.</td>
<td>No outcome instrument used. Difficult to determine why patients were even prescribed braces.</td>
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<tr>
<td>Hseih, et al., 1992</td>
<td>I</td>
<td>Subacute LBP (3–24-wk) patients were randomized to manipulation, massage, corset, or TMS. Outcome assessed by ODI &amp; RMQ. 63 patients enrolled in 3-wk study. The manipulation group performed better than massage &amp; TMS groups, &amp; corset better than massage.</td>
<td>Authors found both scales reliable for measuring LBP. Manipulation fared the best in the short-term FU.</td>
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<tr>
<td>Valle-Jones, et al., 1992</td>
<td>I</td>
<td>216 patient w/ LBP of all duration w/ any bone injury or any intervertebral disc pathology. Randomized to lumbar brace or activity modification. Patients then measured pain &amp; disability on a VAS &amp; paracetamol intake. Also competed a subjective assessment of their condition. Study duration was 3 wks. 100% of patients completed trial.</td>
<td>Significantly more improvement in pain at rest, activity, &amp; night in bracing group after Day 7. Fewer analgesics in brace group. Both groups improved over time; the brace group improved faster. No differences brm groups. All patients enrolled into the study were drawn from a chiropractic clinic.</td>
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<tr>
<td>Pope, et al., 1994</td>
<td>I</td>
<td>164 patients w/ subacute LBP randomized to 1 of 4 treatments: 1) chiropractic manipulation; 2) TMS; 3) massage; &amp; 4) corset. 2:1 randomization w/ 70 patients in Group 1 &amp; 31 in each of the other 4. Assessed as VAS for pain &amp; functional ROM w/ no differences among the groups at 3 wks. Compliance rate was 88% &amp; there were no intergroup differences in pain or function.</td>
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<td>Jellema, et al., 2002</td>
<td>II</td>
<td>Observational study examining usage rates &amp; improvement in symptoms for home health workers w/ LBP. Semi-rigid support worn for 6 mos. Monthly assessments of pain (VAS), disability (Quebec Back Pain Disability Scale), &amp; subjective benefit on a 10-point scale. 80% of patients compliant w/ the brace.</td>
<td>44% decrease in back pain. Individuals rated benefit as 7/10.</td>
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* IVDD = intervertebral disc disease; RMQ = Roland–Morris Questionnaire; RTWS = return-to-work status; SLR = straight leg raising; spondylo = spondylolisthesis.
### Summary of studies involving the use of TEPF

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<th>Authors &amp; Year</th>
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<tr>
<td>Olerud, et al., 1986</td>
<td>III</td>
<td>Reported on the use of the TEPF in 18 patients w/LBP. An improvement was noted w/VAS, pain diagrams, &amp; mobility w/the fixation in place, but no correlation was made w/subsequent fusion.</td>
<td>The authors noted it was a useful test in patients w/a previous fusion who still had pain. All 8 patients in this category improved w/external fixation.</td>
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<tr>
<td>Esses, et al., 1989</td>
<td>III</td>
<td>35 patients w/varying diagnoses for LBP had external fixation for 1–2 wks. They also had a period of time w/the brace loosened (“a placebo trial”). 27/35 subjectively improved w/bracing &amp; they were offered op w/fusion performed using a variety of techniques. Some FU is available for 23 of the patients w/6 patients reporting complete relief, 11 significant relief, 5 no change, &amp; 1 was worse. Fisher exact test: there is a strong association b/w pain relief w/external fixation &amp; positive outcome of subsequent fusion.</td>
<td>No data given on degree of pain relief or who was selected for external fixation. The authors also try to compare external fixation w/radiographic changes, discography, &amp; facet blocks, drawing the conclusion that external fixation is more reliable than these studies.</td>
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<tr>
<td>Ordeberg, et al., 1993</td>
<td>III</td>
<td>FU study of patients from the original series by Olerud. TEPF had been placed for the treatment of LBP. 93 living patients were identified &amp; 63 that were significantly improved were available for review by an independent reviewer. Only 35 (56%) still felt they were improved w/13 unchanged &amp; 15 worse.</td>
<td>Long-term prognostic value of the test not as good as the short-term results. In the paper it is unclear why only 63 patients were available for FU &amp; the measure of pain was subjective throughout the study.</td>
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<tr>
<td>Soini, et al., 1993</td>
<td>III</td>
<td>42 patients w/various diagnoses underwent TEPF. Pain was followed using VAS &amp; function using ODI. 29 patients had a marked relief of pain &amp; had ALIF w/the external frame left in place for a mean of 14 wks. At 2 yrs, 22 were available for FU &amp; had a statistically significant improvement in back &amp; leg pain as well as in ODI in the patients w/a solid fusion.</td>
<td>Overall fusion rate was 83% w/greater improvement in back &amp; leg pain as well as in ODI in the patients w/a solid fusion.</td>
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<td>Soini &amp; Seitsalo, 1993</td>
<td>III</td>
<td>25/100 patients had 30 complications w/18% having pin tract infections. Must carefully consider risk–benefits of the test.</td>
<td>Must carefully consider risk–benefits of the test.</td>
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<tr>
<td>Jeanneret, et al., 1994</td>
<td>II</td>
<td>101 patients w/disabling LBP underwent TEPF. In 47 the pain was relieved &amp; returned after loosening of the external fixator, in 2 the pain remained absent, &amp; in 52 the pain did not change w/external fixation. 42 (34 w/a positive result from external fixation &amp; 8 w/o relief) went on to fusion via several techniques &amp; had 2-yr FU that confirmed fusion. Outcomes were rated good if pain was well controlled, fair if pain had decreased but was still a problem, &amp; poor if pain was worse or unchanged. In patients who had pain relief w/external fixation, 14 (41%) patients were good, 12 (35.5%) were fair, &amp; 8 were poor (23.5%). Of the 8 w/no relief on external fixation, 7 were poor, &amp; 1 was good.</td>
<td>The degree of pain relief was subjectively judged &amp; the complication rate was 17%. Also the selection of nonresponders for fusion is not clear. If good &amp; fair outcomes are seen as a positive response to fusion, external fixation has a sensitivity of 96%, specificity of 47%, PPV of 76%, &amp; an NPV of 88%. If only the good responses are judged a positive outcome, the test has a sensitivity 93%, specificity of 26%, PPV of 41%, &amp; an NPV of 87%.</td>
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<td>Bednar, 2001</td>
<td>III</td>
<td>61 patients considered for lumbar fusion based on positive discography or facet blocks, randomized to fusion (31) or TEPF (30) followed by fusion if the fixator relieved the pain. 1991 (61%) had significant relief of pain following fusion in Group I &amp; 19/21 (90%) of Group II had significant pain relief. The other 9 in Group II had no pain relief &amp; were excluded from further consideration for fusion.</td>
<td>Statistically significant reduction in pain score &amp; analgesic use in the study group. Study was designed to determine the efficacy of external fixation in conjunction w/other diagnostic tests.</td>
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<tr>
<td>van der Schaaf, et al., 1999</td>
<td>III</td>
<td>133 patients w/1 yr of incapacitating LBP of no clear cause. VAS &amp; working capacity were assessed before &amp; for 7–10 days during TEPF. Patients w/a significant relief of pain following fixation &amp; return of pain w/the rigid frame loosened were then offered fusion. 55 patients had fusion &amp; at 2-yr FU had a continued reduction in pain (77 vs 42) that was significant compared w/baseline &amp; the control nonfusion group.</td>
<td>Patient satisfaction in the fusion group was high. Authors concluded that when pain is relieved w/external fixation, the subsequent fusion over the tested levels will likely be successful in relieving pain. There was a 9.8% infection rate &amp; a 9% root irritation rate.</td>
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<tr>
<td>Bednar, 2001</td>
<td>III</td>
<td>100 patients underwent TEPF for 1–2 wks w/VAS &amp; Prolo score recorded prior to &amp; at the completion of trial. 60 had adequate pain relief &amp; were offered fusion. 49 had PLF w/instrumentation. 55% had improvement in their Prolo score, 37% no change, &amp; 8% were worse.</td>
<td>Pooled data from 5 other series &amp; found definitive long-term relief in only 36% of patients (173482). These include all patients subjected to external fixation, not just “responders.”</td>
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<td>Axelsson, et al., 2003</td>
<td>III</td>
<td>Observational study of 26 patients w/LBP who had TEPF placed for 8 days. Patients had a variety of diagnoses &amp; were selected for fusion based on a decrease in pain &amp; ALD &amp; 2 functional walking tests. 20 patients went on to fusion &amp; 14 had good, 4 fair, &amp; 2 poor outcomes. The conclusion was that a trial of external fixation led to improved selection of patients who had fusion for LBP based on the fact that 70% of patients had a good outcome.</td>
<td>Difficult to determine which patients had a “positive response” to external fixation. The outcome criteria were a patient-based satisfaction survey. Wide variety of diagnoses were in the study which makes it impossible to subdivide based on cause.</td>
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* ADL = activities of daily living; ALIF = anterior lumbar interbody fusion.
Brace therapy in lumbar degenerative disease

using a VAS and were also assessed for ROM after 3 weeks of treatment. There were no differences among the groups. Because of the relatively small treatment groups (~30 patients in three of the four groups) and selected patient population (from a chiropractic practice), this paper is considered to provide Class II medical evidence suggesting that braces are not an effective treatment for low-back pain. Valle-Jones and colleagues²⁰ randomized 216 patients with non-specific low-back pain of varying duration to lumbar brace therapy or activity modification for 3 weeks. Outcome measures included a VAS score for pain and disability. Patients were also asked to record usage of pain medication. Brace-treated patients were found to have more improvement in pain at rest, pain with activity, and pain at night between Days 7 and 21. In addition, brace-treated patients took 50% of the analgesics of those in the activity modification group over the 3-week period. This paper is considered to provide Class I medical evidence supporting the efficacy of braces for the short-term amelioration of low-back pain. With regard to the chronic low-back pain population, the evidence provided by this report would be considered Class III because of the inclusion of many patients with relatively acute symptoms. Hseih and associates²³ studied 63 patients with low-back pain of less than 6 months' duration. Patients were randomized to either manipulation, massage, lumbar corset, or TMS treatment for 3 weeks. Functional outcomes were assessed by ODI and Roland–Morris questionnaires. Patients treated with corsets had significantly better outcomes than those in the manipulation group on both scales, but they were not functionally improved compared with those in the manipulation or TMS groups. This paper provides Class I medical evidence supporting the role of short-term lumbar brace therapy in patients with acute or subacute low-back pain. No inferences can be drawn regarding the effect of braces among the chronic low-back pain population.

Two randomized controlled studies published in 1981 provide information on lumbar brace therapy for low-back pain. Coxhead and coworkers¹⁰ performed a randomized study of 322 sciatica patients with or without low-back pain randomized to different treatment modalities including traction, exercises, manipulation, corset brace, and combinations of these treatments for a total of 16 treatment groups. Treatments lasted for 4 weeks and outcome was assessed at 1, 4, and 16 months by VAS, return-to-work status, and patient satisfaction criteria. No benefit, short or long term, was detected for the use of lumbar corset braces. Because the population was composed of patients with sciatica, the medical evidence in this report against the efficacy of brace therapy for low-back pain is considered Class III. In a smaller study of 19 patients with chronic low-back pain, Million, et al.²⁵ performed a study of 5 patients with either a soft or rigid lumbar brace group for 4 weeks. A 15-item questionnaire about pain and functional limitation on a VAS (Million Scale) demonstrated a significant improvement (p < 0.01) for patients wearing a rigid brace at 4 and 8 weeks. Rigid lumbar bracing may therefore have some short-term benefit compared with soft bracing for the short-term treatment of low-back pain. Because there was no control group in this study, the paper is considered to provide Class III medical evidence regarding the efficacy of brace therapy for low-back pain.

One study reported in the literature specifically exam-
ined the use of preoperative brace therapy as a predictive test for outcome following lumbar fusion. Axelsson, et al.,6 placed all patients who were to undergo a lumbar fusion for low-back pain in either a rigid or a semirigid brace for at least 3 weeks. Pain improvement was recorded and a significant response was judged to be an improvement in pain of at least 50%. Only 50 patients with a solid radiographic fusion at 1 year were included in the study. Two years following surgery, these same patients were subjectively examined for pain relief and satisfaction. Thirty-one patients had improved pain scores and 20 of these had a good outcome at 2 years (pain free or significant improvement), whereas 11 patients had poor outcomes despite a favorable response to preoperative lumbar bracing. Nineteen patients did not have significant relief and 13 of these reported a favorable outcome at 2 years. If lumbar bracing is used as a preoperative “prognostic test” for success after solid fusion, the sensitivity is 61%, the specificity is 35%, the PPV is 65%, and the NPV is 32%. Therefore, the use of lumbar bracing as a preoperative adjunct to predict the outcome of fusion is not recommended. Because of the reliance on patient satisfaction scores, the select population studied (only patients with solid radiographic fusion), and the use of several types of braces in the preoperative period, the medical evidence derived from this study is considered Class III.

Although originally described as a technique for reduction and fixation of thoracolumbar fractures,12–14 TEPF has been used to predict the response to lumbar fusion in patients with low-back pain.1,6,12-20,31,37 Several studies have examined the ability of TEPF to predict outcome following lumbar fusion. Axelsson, et al.,6,16 described their experience in treating 26 patients with low-back pain (with a variety of diagnoses) who underwent TEPF for 8 days. Patients were selected for lumbar fusion if they reported a decrease in pain while performing five activities of daily living and demonstrated improvement in two functional walking tests. Twenty patients reported improvement and were treated with lumbar fusion. Fourteen reported a good outcome, four reported a fair outcome, and two patients reported their outcome as poor. The authors concluded that 70% of their patients achieved good outcomes and therefore that a trial of TEPF led to better selection of patients with low-back pain who might benefit from lumbar fusion surgery.1 Because no comparison was made with a control group (patients who did not have pain relief with TEPF or those who did not undergo TEPF) was described, no meaningful conclusions regarding the efficacy of TEPF in this population can be drawn.

Bednar7 noted that only 55% of 49 patients who experienced pain relief after TEPF and subsequent instrumentation-based PLF had improvement in their Prolo Scale score. Thirty-seven percent reported no change in their Prolo Scale scores following surgery and 8% were worse. Other authors have provided Class III medical evidence for the use of TEPF as a preoperative test to predict outcome from lumbar fusion. In all of the studies cited, only patients with a positive response to TEPF were selected for lumbar fusion. The methods used to evaluate the response to TEPF and to evaluate the success of surgery vary from study to study.12-14,30,34,36,37,39,41

One report includes outcome data obtained in patients who were nonresponders to a trial of TEPF but who nonetheless underwent lumbar fusion surgery.16 One hundred one patients with disabling low-back pain underwent placement of external fixation. Forty-seven patients had relief of pain due to TEPF that recurred after loosening of the external fixator device. Two patients had lasting relief of their pain even when the fixator was removed. Fifty-two patients did not have pain relief with TEPF. Forty-two patients underwent successful lumbar fusion (a variety of techniques were used); 34 experienced pain relief with TEPF and eight underwent surgery despite an absent response to TEPF. Outcomes were determined using a patient satisfaction scale. Of patients who had pain relief with external fixation, 14 (41%) reported good results, 12 (35.5%) reported fair results, and eight (23.5%) reported poor results. Of the eight patients with no relief, seven reported poor results and one reported a good result. If good and fair outcomes are grouped as a positive response, TEPF-related pain relief has a 96% sensitivity, 47% specificity, 76% PPV, and 88% NPV for predicting response to fusion. If only good outcomes are considered as positive, the corresponding values are 93, 26, 41, and 87%. The medical evidence provided by this report is considered Class III because the outcome scale used is nonvalidated, the criteria used to determine the occurrence of successful fusion are unclear, and the indications for fusion among patients who did not respond to TEPF were not described.

The complication rate of TEPF is not low. Soini and Seitsalo35 reported a 25% complication rate, including infection, nerve root irritation, and spinal fluid leakage. In another report of TEPF the authors cited infection rates of 10% or greater and complication rates approaching 20%.14 Because of the significant complication rate and the uncertainty of TEPF in predicting a good outcome following lumbar fusion, TEPF is not recommended as a routine screening modality for the success of lumbar fusion surgery in patients suffering from low-back pain.

Several authors have advocated the use of brace therapy following lumbar fusion surgery;6,19 however, there are no published studies that compared outcomes following lumbar fusion with and without the supplemental use of a lumbar orthosis. Johnson, et al.,26 have suggested a minimum 5-month period of bracing following noninstrumented lumbar fusion. They noted that patients assessed 6 months following surgery with RSA had a higher fusion rate (eight of 11 patients) at 1 year compared with 3 months (two of 11). The authors found that sagittal and vertical translation decreased significantly as measured by RSA between 3 and 6 months following surgery. They interpreted this result as evidence that healing of a noninstrumented lumbar fusion occurs over a 6-month time period. They presented no evidence, however, regarding the effect of lumbar bracing on the rate of lumbar spinal fusion or functional outcome.

Summary

Although conflicting reports have been presented in the literature regarding the utility of lumbar braces for the prevention of low-back pain, most Class III medical evidence suggests that these supports used prophylactically do not reduce the incidence of low-back pain or decrease the
Brace therapy in lumbar degenerative disease

amount of time lost from work in the general working population. Among workers with a history of a back injury, their use appears to decrease the number of work days lost due to back pain. Lumbar braces appear to be an effective treatment for acute low-back pain in some populations. They do not appear to be effective in the chronic low-back pain population. If a brace is used, rigid braces offer some benefit over soft braces.

There are no data to suggest that relief of low-back pain with preoperative external bracing predicts a favorable outcome following lumbar spinal fusion. No information is available on the benefit of bracing for improving fusion rates or clinical outcomes following instrumented lumbar fusion for degenerative disease.

Key Directions for Future Research

The most relevant questions for the spine surgeon may be related to the ability of a trial of brace therapy to predict functional outcomes following lumbar fusion surgery and the ability of postoperative braces to improve functional and radiographic outcomes. The first issue could be resolved by randomizing half of a population of patients already selected for surgery to a trial of bracing prior to lumbar fusion surgery. The results of surgery could then be compared with the results of bracing. Depending on the methods of patient allocation and outcome measures, Class I or II medical evidence could be derived. To determine the efficacy of postoperative bracing, a comparison between patients undergoing similar lumbar fusion procedures, randomized to brace therapy or no such therapy, would provide high-quality evidence to support or refute the hypothesis that bracing improves fusion rates and/or functional outcome following lumbar fusion procedures in the treatment of lumbar degenerative disease.

References


