

MEDICAL CONTESTED CASE HEARING NO. 13115

DECISION AND ORDER

This case is decided pursuant to Chapter 410 of the Texas Workers' Compensation Act and Rules of the Division of Workers' Compensation adopted thereunder.

ISSUES

A contested case hearing was held on July 24, 2013 to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the decision of the IRO that the Claimant is not entitled to inpatient mini 360 lumbar fusion with 2 day hospital stay for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by EM, ombudsman.
Respondent/Carrier appeared and was represented by WS, attorney.

BACKGROUND INFORMATION

Claimant is a 39-year-old patrol officer for Employer city who was injured on (Date of Injury) while participating in training for the SWAT team. Claimant said that he was wearing a heavy duty armor vest which pounded him in his lower back while he trained, causing injury to the lumbar spine. Claimant has had a gap in treatment from 2008 to 2012 during which he was not under the care of a physician and took only over-the-counter medications. His back symptoms worsened in 2012 and Claimant was seen by Dr. C, M.D. at (Healthcare Provider) who ordered a repeat MRI which showed that Claimant has an L5-S1 disc herniation on the right which was now larger than that shown on MRI 4 years previously. Claimant had conservative care including physical therapy, medication management, epidural injections and facet injections. He was referred to surgeon Dr. S, M.D. who has recommended the disputed treatment which involves a combined anterior and posterior fusion at the L5-S1 level. Dr. S cited an FDA study which evaluated disc replacement versus fusion. The study was not offered into evidence. She contends that Claimant meets the criteria for that study and would benefit from either a disc replacement or a fusion. Dr. S did not contend that Claimant meets the patient selection criteria for spinal fusion set out in the Official Disability Guidelines (ODG).

Texas Labor Code Section 408.021 provides that an employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed. Health care reasonably required is further defined in Texas Labor Code Section 401.011

(22a) as health care that is clinically appropriate and considered effective for the injured employee's injury and provided in accordance with best practices consistent with evidence based medicine or, if evidence based medicine is not available, then generally accepted standards of medical practice recognized in the medical community. Health care under the Texas Workers' Compensation system must be consistent with evidence based medicine if that evidence is available. Evidence based medicine is further defined in Texas Labor Code Section 401.011 (18a) to be the use of the current best quality scientific and medical evidence formulated from credible scientific studies, including peer-reviewed medical literature and other current scientifically based texts and treatment and practice guidelines. The Commissioner of the Division of Workers' Compensation is required to adopt treatment guidelines that are evidence-based, scientifically valid, outcome-focused and designed to reduce excessive or inappropriate medical care while safeguarding necessary medical care. Texas Labor Code Section 413.011(e). Medical services consistent with the medical policies and fee guidelines adopted by the commissioner are presumed reasonable in accordance with Texas Labor Code Section 413.017(1).

In accordance with the above statutory guidance, the Division of Workers' Compensation has adopted treatment guidelines by Division Rule 137.100. This rule directs health care providers to provide treatment in accordance with the current edition of the Official Disability Guidelines (ODG), and such treatment is presumed to be health care reasonably required as defined in the Texas Labor Code. Thus, the focus of any health care dispute starts with the health care set out in the ODG. Also, in accordance with Division Rule 133.308 (s), "A decision issued by an IRO is not considered an agency decision and neither the Department nor the Division are considered parties to an appeal. In a Contested Case Hearing (CCH), the party appealing the IRO decision has the burden of overcoming the decision issued by an IRO by a preponderance of evidence-based medical evidence."

The ODG provides as follows relating to Spinal Fusion Surgery:

Not recommended for patients who have less than six months of failed recommended conservative care unless there is objectively demonstrated severe structural instability and/or acute or progressive neurologic dysfunction, but recommended as an option for spinal fracture, dislocation, spondylolisthesis or frank neurogenic compromise, subject to the selection criteria outlined in the section below entitled, "Patient Selection Criteria for Lumbar Spinal Fusion," after 6 months of conservative care. For workers' comp populations, see also the heading, "Lumbar fusion in workers' comp patients." After screening for psychosocial variables, outcomes are improved and fusion may be recommended for degenerative disc disease with spinal segment collapse with or without neurologic compromise after 6 months of compliance with recommended conservative therapy. [For spinal instability criteria, see AMA Guides For

complete references, see separate document with all studies focusing on Fusion (spinal). There is limited scientific evidence about the long-term effectiveness of fusion for degenerative disc disease compared with natural history, placebo, or conservative treatment. Studies conducted in order to compare different surgical techniques have shown success for fusion in carefully selected patients.

According to the recently released AANS/NASS Guidelines, lumbar fusion is recommended as a treatment for carefully selected patients with disabling low back pain due to one- or two-level degenerative disc disease after failure of an appropriate period of conservative care. This recommendation was based on one study that contained numerous flaws, including a lack of standardization of conservative care in the control group. At the time of the 2-year follow up it appeared that pain had significantly increased in the surgical group from year 1 to 2. Follow-up post study is still pending publication. In addition, there remains no direction regarding how to define the “carefully selected patient.” A recently published well respected international guideline, the “European Guidelines,” concluded that fusion surgery for nonspecific chronic LBP cannot be recommended unless 2 years of all other recommended conservative treatments – including multidisciplinary approaches with combined programs of cognitive intervention and exercises – have failed, or such combined programs are not available, and only then in carefully selected patients with maximum 2-level degenerative disc disease. For chronic LBP, exercise and cognitive intervention may be equivalent to lumbar fusion without the potentially high surgical complication rates. In acute spinal cord injury (SCI), if the spine is unstable following injury, surgical fusion and bracing may be necessary. A study on improving quality through identifying inappropriate care found that use of guideline-based Utilization Review (UR) protocols resulted in a denial rate for lumbar fusion 59 times as high as denial rates using non-guideline based UR. The profit motive and market medicine have had a significant impact on clinical practice and research in the field of spine surgery. Data on geographic variations in medical procedure rates suggest that there is significant variability in spine fusion rates, which may be interpreted to suggest a poor professional consensus on the appropriate indications for performing spinal fusion. Outcomes from complicated surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. Despite the new technologies, reoperation rates after lumbar fusion have become higher. According to the recent Medicare Coverage Advisory Committee Technology Assessment, the evidence for lumbar spinal fusion does not conclusively demonstrate short-term or long-term benefits compared with nonsurgical treatment for elderly patients. When lumbar fusion surgery is performed, either with lateral fusion alone or with interbody fusion, unlike cervical fusion, there is no absolute contraindication to

patients returning even to contact sports after complete recovery from surgery. Like patients with a thoracic injury, those with a lumbar injury should be pain free, have no disabling neurological deficit, and exhibit evidence of bone fusion on x-ray films before returning. A recent randomized controlled trial comparing decompression with decompression and instrumented fusion in patients with foraminal stenosis and single-level degenerative disease found that patients universally improved with surgery, and this improvement was maintained at 5 years. However, no obvious additional benefit was noted by combining decompression with an instrumented fusion. Discography may be supported if the decision has already been made to do a spinal fusion, and a negative discogram could rule out the need for fusion on that disc (but a positive discogram in itself would not justify fusion). Discography may help distinguish asymptomatic discs among morphologically abnormal discs in patients without psychosocial issues. Precise prospective categorization of discographic diagnoses may predict outcomes from treatment, surgical or otherwise. New research shows that healthcare expenditures for back and neck problems have increased substantially over time, but with little improvement in healthcare outcomes such as functional disability and work limitations. Rates of imaging, injections, opiate use, and spinal surgery have increased substantially over the past decade, but it is unclear what impact, if any, this has had on health outcomes. The efficacy of surgery for nonspecific back pain is uncertain. There may be some patients for whom surgery, fusion specifically, might be helpful, but it is important for doctors to discuss the fact that surgery doesn't tend to lead to huge improvements on average, about a 10- to 20-point improvement in function on a 100-point scale, and a significant proportion of patients still need to take pain medication and don't return to full function. This study showed that fusion for chronic lower back pain was the least successful common orthopaedic surgery. The study compared the gains in quality of life achieved by total hip replacement, total knee replacement, surgery for spinal stenosis, disc excision for lumbar disc herniation, and arthrodesis for chronic low back pain. For chronic lower back pain, improvements were statistically significant but clinically negligible. Although pain was reduced and function improved slightly, outcomes remained in the moderately affected range, quality of life was not improved and rendered worse, on average. While surgery for spinal stenosis and for disc herniation compare well with archetypical orthopaedic operations, the outcomes of surgery for chronic lower back pain do not even approach those of other orthopaedic procedures, and the data show that patients with back pain are rendered worse off by surgery. Recent studies document a 220% increase in lumbar spinal fusion surgery rates, without demonstrated improvements in patient outcomes or disability rates. In a study of 2,378 Washington State workers' compensation claimants who underwent fusion

to assess the frequency, timing, and causes of death, the 3-year cumulative mortality rate post-fusion was 1.93% and analgesic-related deaths were responsible for 21% of all deaths and 31.4% of all potential life lost. A study to compare the surgical experience, clinical outcomes, and effect on body weight between obese and morbidly obese patients undergoing lumbar spine fusion surgery concluded that clinical outcomes were independent of the BMI of the patient, but the incidence of postoperative complications was significant in 45% of morbidly obese and 44% of obese patients. The authors proposed that morbidly obese patients should undergo bariatric surgery before spine surgery in nonemergent situations. For nonradicular low back pain with common degenerative changes, there is fair evidence that fusion is no better than intensive rehabilitation with a cognitive-behavioral emphasis for improvement in pain or function, and less than half of patients experience optimal outcomes (defined as no more than sporadic pain, slight restriction of function, and occasional analgesics) following fusion. Posterolateral bone-grafting fusion is not necessary when a Denis type-B thoracolumbar burst fracture associated with a load-sharing score of ≤ 6 is treated with short-segment pedicle screw fixation. Discography (and not merely the fusion) may actually be the cause of adjacent segment disc degeneration. This study suggested that the phenomenon of accelerated adjacent segment degeneration adjacent to fusion levels may be, in part, explained by previous disc puncture if discography was used in segments adjacent to the fusion. Among Medicare recipients, the frequency of complex fusion procedures for spinal stenosis increased 15-fold in just 6 years. The introduction and marketing of new surgical devices and financial incentives may stimulate more invasive surgery. Results of this study suggest that postmenopausal female patients who underwent lumbar spinal instrumentation fusion were susceptible to subsequent vertebral fractures within 2 years after surgery (in 24% of patients). A four-year follow-up of an RCT of instrumented transpedicular fusion versus cognitive intervention and exercises for disc degeneration with chronic low back pain concluded that this invasive and high-cost procedure does not afford better outcomes compared with the conservative treatment approach to low back pain, and this study should give doctors pause when recommending lumbar fusion surgery without compelling indications, particularly when strong back rehabilitation programs are available. The ECRI health technology assessment concluded that the evidence is insufficient to support lumbar fusion being more effective (to a clinically meaningful degree) than nonsurgical treatments (intensive exercise and rehabilitation plus cognitive behavioral therapy) in patients with and without prior surgery. There is a high rate of complications (56.4%) in spinal fusion procedures, especially related to instrumentation. The draft AHRQ Comparative Effectiveness Research concluded that limited data

suggests that fusion leads to greater improvement in back pain relief and function than physical therapy at 2-year followup, but whether the difference is clinically significant is unclear, and serious adverse events occurred in the fusion group but not the noninvasive-intervention group. Lumbar spinal fusion surgeries use bone grafts, and are sometimes combined with metal devices, to produce a rigid connection between two or more adjacent vertebrae. The therapeutic objective of spinal fusion surgery for patients with low back problems is to prevent any movement in the intervertebral spaces between the fused vertebrae, thereby reducing pain and any neurological deficits. See also Adjacent segment disease/degeneration (fusion) & Iliac crest donor-site pain treatment.

Lumbar fusion in workers' comp patients: In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, which should be considered. Until further research is conducted there remains insufficient evidence to recommend fusion for chronic low back pain in the absence of stenosis and spondylolisthesis, and this treatment for this condition remains “under study.” It appears that workers' compensation populations require particular scrutiny when being considered for fusion for chronic low back pain, as there is evidence of poorer outcomes in subgroups of patients who were receiving compensation or involved in litigation. Despite poorer outcomes in workers' compensation patients, utilization is much higher in this population than in group health. Presurgical biopsychosocial variables predict patient outcomes from lumbar fusion, which may help improve patient selection. Workers' compensation status, smoking, depression, and litigation were the most consistent presurgical predictors of poorer patient outcomes. Other predictors of poor results were number of prior low back operations, low household income, and older age. Obesity and litigation in workers' compensation cases predict high costs associated with interbody cage lumbar fusion. A recent study of 725 workers' comp patients in Ohio who had lumbar fusion found only 6% were able to go back to work a year later, 27% needed another operation, and over 90% were in enough pain that they were still taking narcotics at follow-up. A recent case-control study of lumbar fusion outcomes in worker's compensation (WC) patients concluded that only 9% of patients receiving WC achieved substantial clinical benefit compared to 33% of those not receiving WC. This large historical cohort study suggests that lumbar fusion may not be an effective operation in workers' compensation patients with disc degeneration, disc herniation, and/or radiculopathy, and it is associated with significant increase in disability, opiate use, prolonged work loss, and poor RTW status. After controlling for covariates known to affect lumbar fusion outcomes, patients on workers' comp have significantly less improvement. The presidents of AAOS, NASS, AANS, CNS, and SAS issued a joint statement to BlueCross

BlueShield recommending patient selection criteria for lumbar fusion in degenerative disc disease. The criteria included at least one year of physical and cognitive therapy, inflammatory endplate changes (i.e., Modic changes), moderate to severe disc space collapse, absence of significant psychological comorbidities (e.g. depression, somatization disorder), and absence of litigation or compensation issues. The criteria of denying fusion if there are compensation issues may apply to workers' compensation patients. On the other hand, a separate policy statement from the International Society for the Advancement of Spine Surgery disagrees that worker's compensation should be a contraindication for lumbar fusion. This study demonstrated a significant difference in outcomes after lumbar spinal fusion between workers' comp populations and those on long-term disability insurance. Both populations only achieved marginal improvement, but workers' comp had a clear, negative influence on outcome even when compared to disability patients.

Lumbar fusion for spondylolisthesis: Recommended as an option for spondylolisthesis. Patients with increased instability of the spine after surgical decompression at the level of degenerative spondylolisthesis are candidates for fusion. This study found only a 27% success from spinal fusion in patients with low back pain and a positive single-level low-pressure provocative discogram, versus a 72% success in patients having a well-accepted single-level lumbar pathology of unstable spondylolisthesis. Unilateral instrumentation used for the treatment of degenerative lumbar spondylolisthesis is as effective as bilateral instrumentation. Patients with degenerative spondylolisthesis and spinal stenosis who undergo standard decompressive laminectomy (with or without fusion) showed substantially greater improvement in pain and function during a period of 2 years than patients treated nonsurgically, according to the recent results from the Spine Patient Outcomes Research Trial (SPORT). For degenerative lumbar spondylolisthesis, spinal fusion may lead to a better clinical outcome than decompression alone. No conclusion about the clinical benefit of instrumenting a spinal fusion can be made, but there is moderate evidence that the use of instrumentation improves the chance of achieving solid fusion. A recent systematic review of randomized trials comparing lumbar fusion surgery to nonsurgical treatment of chronic back pain associated with lumbar disc degeneration, concluded that surgery may be more efficacious than unstructured nonsurgical care but may not be more efficacious than structured cognitive-behavior therapy. Methodological limitations of the randomized trials prevented firm conclusions. A comparison of surgical and nonoperative outcomes between degenerative spondylolisthesis and spinal stenosis patients from the SPORT trial found that fusion was most appropriate for spondylolisthesis, with or without listhesis, and decompressive laminectomy alone most appropriate for spinal stenosis. The latest SPORT study concluded that leg pain is associated with better

surgical fusion outcomes in spondylolisthesis than low back pain. Comparative effectiveness evidence from SPORT shows good value for laminectomy and/or bilateral single-level fusion after an imaging-confirmed diagnosis of degenerative spondylolisthesis [as recommended in ODG], compared with nonoperative care over 4 years.

Lumbar fusion for Scheuermann's kyphosis: Recommended as an option for adult patients with severe deformities (e.g. more than 70 degrees for thoracic kyphosis), neurological symptoms exist, and pain cannot be adequately resolved non-operatively (e.g. physical therapy, back exercises). Good outcomes have been found in a relatively large series of patients undergoing either combined anterior-posterior or posterior only fusion for Scheuermann's kyphosis.

Patient Selection Criteria for Lumbar Spinal Fusion:

For chronic low back problems, fusion should not be considered within the first 6 months of symptoms, except for fracture, dislocation or progressive neurologic loss. Indications for spinal fusion may include:

- (1) Neural Arch Defect - Spondylolytic spondylolisthesis, congenital neural arch hypoplasia.
- (2) Segmental Instability (objectively demonstrable) - Excessive motion, as in degenerative spondylolisthesis, surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after surgical discectomy, with relative angular motion greater than 20 degrees.
- (3) Primary Mechanical Back Pain (i.e., pain aggravated by physical activity)/Functional Spinal Unit Failure/Instability, including one or two level segmental failure with progressive degenerative changes, loss of height, disc loading capability. In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, which should be considered. There is a lack of support for fusion for mechanical low back pain for subjects with failure to participate effectively in active rehab pre-op, total disability over 6 months, active psych diagnosis, and narcotic dependence. Spinal instability criteria includes lumbar inter-segmental movement of more than 4.5 mm.
- (4) Revision Surgery for failed previous operation(s) if significant functional gains are anticipated. Revision surgery for purposes of pain relief must be approached with extreme caution due to the less than 50% success rate reported in medical literature.
- (5) Infection, Tumor, or Deformity of the lumbosacral spine that cause intractable pain, neurological deficit and/or functional disability.

- (6) After failure of two discectomies on the same disc, fusion may be an option at the time of the third discectomy, which should also meet the ODG criteria.

(See ODG Indications for Surgery -- Discectomy.)

Pre-Operative Surgical Indications Recommended: Pre-operative clinical surgical indications for spinal fusion should include all of the following:

- (1) All pain generators are identified and treated; &
- (2) All physical medicine and manual therapy interventions are completed; &
- (3) X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or discography (see discography criteria) & MRI demonstrating disc pathology correlated with symptoms and exam findings; &
- (4) Spine pathology limited to two levels; &
- (5) Psychosocial screen with confounding issues addressed.
- (6) For any potential fusion surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing.

For average hospital LOS after criteria are met, see Hospital length of stay (LOS).

The IRO reviewer as well as the Carrier's utilization reviewers in this case have relied on the ODG as evidence based medicine which contraindicates the requested fusion procedure. In this regard, it was emphasized that no instability was documented by flexion and extension x-rays, no radicular complaints and no neurological deficits. The ODG is the only evidence based medical evidence which is in evidence in this case and it is evident that Claimant does not meet the criteria for the proposed fusion surgery.

Even though all the evidence presented was not discussed, it was considered. The Findings of Fact and Conclusions of Law are based on all of the evidence presented.

FINDINGS OF FACT

1. The parties stipulated to the following facts:
 - A. Venue is proper in the (City) Field Office of the Texas Department of Insurance, Division of Workers' Compensation.
 - B. On (Date of Injury), Claimant was the employee of (Self-Insured), Employer.
 - C. On (Date of Injury), Employer furnished workers' compensation coverage through self insurance.
 - D. Claimant sustained a compensable injury on (Date of Injury).

- E. The IRO determined that Claimant is not entitled to inpatient mini 360 lumbar fusion with 2 day hospital stay for the compensable injury of (Date of Injury).
2. Carrier delivered to Claimant and Provider a single document stating the true corporate name of Carrier, and the name and street address of Carrier's registered agent, which document was admitted into evidence as Hearing Officer's Exhibit Number 2.
 3. Inpatient mini 360 lumbar fusion with 2 day hospital stay is not health care reasonably required for the compensable injury of (Date of Injury).

CONCLUSIONS OF LAW

1. The Texas Department of Insurance, Division of Workers' Compensation, has jurisdiction to hear this case.
2. Venue is proper in the (City) Field Office.
3. The preponderance of the evidence is not contrary to the decision of the IRO that inpatient mini 360 lumbar fusion with 2 day hospital stay is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to inpatient mini 360 lumbar fusion with 2 day hospital stay for the compensable injury of (Date of Injury).

ORDER

Carrier is not liable for the benefits at issue in this hearing. Claimant remains entitled to medical benefits for the compensable injury in accordance with §408.021.

The true corporate name of the insurance carrier is **(SELF-INSURED)** and the name and address of its registered agent for service of process is

(SELF-INSURED)
STREET ADDRESS
(CITY), TX (ZIP CODE)

Signed this 29th day of July, 2013

Warren E. Hancock, Jr.
Hearing Officer