

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.

ISSUE

A contested case hearing was held on August 30, 2010, to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that the claimant is not entitled to a total right knee arthroplasty for the compensable injury on _____?

PARTIES PRESENT

The petitioner/claimant appeared and was assisted by PA, ombudsman. The carrier/respondent appeared and was represented by SS, attorney.

BACKGROUND INFORMATION

The claimant sustained a right knee injury following a trip and fall incident on _____. Arthroscopic surgery in February, 2000, during which defects of the medial femoral condyle in the claimant's right knee were shaved and drilled, revealed that there was only "mild chondromalacia of the patella" and that the condition of the lateral compartment was unremarkable. Similarly, an April, 2000 right knee MRI revealed no pathology in the patellar or lateral compartments of the claimant's knee. The claimant had ongoing crepitus and complaints of pain in her knee following the surgery. She has received intermittent conservative care, in the form of medications and injections, between the surgery and the current request for right knee arthroplasty.

On October 21, 2009, orthopedic surgeon Dr. Y, M. D., to whom the claimant had been referred in November, 2008, noted that x-rays showed "some significant medial joint space narrowing, and potentially bone-on-bone arthritis." While he briefly mentioned "some patellofemoral arthritis as well" in a February, 2010 report, his focus was on the medial compartment of the claimant's right knee.

In reviewing Dr. J's request for a total right knee arthroplasty, the first utilization review doctor, an orthopedic surgeon, pointed out that the official disability guides (ODG) require osteoarthritis in two of the three compartments in the knee to support the medical necessity of a total knee replacement. As detailed above, the claimant only has pathology in one compartment, the medial. The first utilization review doctor also cited the lack of information in the record that could be used to determine the claimant's body mass index (BMI)—which the ODG takes into consideration in its discussion of total knee replacements. While the reviewer also cited the lack

of evidence of the failure of conservative care, the medical record introduced at the hearing revealed ongoing pain and crepitus despite injections and medications.

The utilization review doctor who reviewed the request on reconsideration, who is also an orthopedic surgeon, did discuss the conservative care received by the claimant in the form of medications and injections. However, he still determined that there was insufficient evidence of the failure of conservative care due to the lack of evidence of any stretching or strengthening exercises, the lack of any physical therapy notes, and the absence of objective documentation of the claimant's clinical and functional response to the injections received. He concluded that, "The maximum potential of the conservative treatment done was not fully exhausted to indicate a surgical procedure."

An IRO reviewer, an "M. D., board certified orthopedic surgeon with extensive experience in the evaluation and treatment of patients suffering osteoarthritis of the knees", upheld the carrier's denial of total right knee arthroplasty. He first noted that the osteoarthritis in the claimant's right knee principally involved the medial compartment. He maintained that there was no specific documentation of diminished range of motion, no specific mechanical symptoms reported, no documentation of physical therapy, no documentation of the effect of the injections and medications received to that time by the claimant, and insufficient information in the medical records to allow calculation of the claimant's BMI, although from the claimant's recorded weight the IRO reviewer opined that the claimant's "BMI may not meet criteria . . ." for a total knee replacement.

DISCUSSION

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 (t), "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."

On the date of this medical contested case hearing, the ODG provides the following with regard to total knee arthroplasty:

Recommended as indicated below. Total hip and total knee arthroplasties are well accepted as reliable and suitable surgical procedures to return patients to function. The most common diagnosis is osteoarthritis. Overall, total knee arthroplasties were found to be quite effective in terms of improvement in health-related quality-of-life dimensions, with the occasional exception of the social dimension. Age was not found to be an obstacle to effective surgery, and men seemed to benefit more from the intervention than did women. (Ethgen, 2004) Total knee arthroplasty was found to be associated with substantial functional improvement. (Kane, 2005) Navigated knee replacement provides few advantages over conventional surgery on the basis of radiographic end points. (Bathis, 2006) (Bauwens, 2007) The majority of patients who undergo total joint replacement are able to maintain a moderate level of physical activity, and some maintain very high activity levels. (Bauman, 2007) Functional exercises after hospital discharge for total knee arthroplasty result in a small to moderate short-term, but not long-term, benefit. In the short term physical therapy interventions with exercises based on functional activities may be more effective after total knee arthroplasty than traditional exercise programs, which concentrate on isometric muscle exercises and exercises to increase range of motion in the joint. (Lowe, 2007) The safety of simultaneous bilateral total knee replacement remains controversial. Compared with staged bilateral or unilateral total knee replacement, simultaneous bilateral total knee replacement carries a higher risk of serious cardiac complications, pulmonary complications, and mortality. (Restrepo, 2007) Accelerated perioperative care and rehabilitation intervention after hip and knee arthroplasty (including intense physical therapy and exercise) reduced mean hospital length of stay (LOS) from 8.8 days before implementation to 4.3 days after implementation. (Larsen, 2008) In this RCT, perioperative celecoxib (Celebrex) significantly improved postoperative resting pain scores at 48 and 72 hrs, opioid consumption, and active ROM in the first three days after total knee arthroplasty, without increasing the risks of bleeding. The study group received a single 400 mg dose of celecoxib, one hour before surgery, and 200 mg of celecoxib every 12 hours for five days. (Huang, 2008) Total knee arthroplasty (TKA) not only improves knee mobility in older patients with severe osteoarthritis of the knee, it actually improves the overall level of physical functioning. Levels of physical impairment were assessed with three tools: the Nagi Disability Scale, the Instrumental Activities of Daily Living Scale (IADL) and the Activities of Daily Living (ADL) Scale. Tasks on the Nagi Disability Scale involve the highest level of physical functioning, the IADL an intermediate level, and the ADL Scale involves the most basic levels. Statistically significant average treatment effects for TKA were observed for one or more tasks for each measure of physical functioning. The improvements after TKA were "sizeable" on

all three scales, while the no-treatment group showed declining levels of physical functioning. (George, 2008) This study showed that total knee replacement is second the most successful orthopaedic procedure for relieving chronic pain, after total hip. 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. Hip replacement reduced pain to levels normal for age, reduced physical functioning to within 75% normal levels, and restored quality of life to virtually normal levels. Total knee replacement was the next most successful procedure, and it all but eliminated pain, improved physical functioning to 60% normal, and restored quality of life to within 65% of normal. (Hansson, 2008) A 6-week program of progressive strength training targeting the quadriceps femoris muscle group substantially improves strength and function following total knee arthroplasty for treatment of osteoarthritis, compared to patients who received standard of care therapy; however, addition of neuromuscular electrical stimulation (NMES) to the strength training exercise did not improve outcomes. (Pettersen, 2009) Knee replacement surgery is expensive but worth the cost, especially if performed by experienced surgeons, according to a recent study. Some \$11 billion is spent on 500,000 total knee replacements each year in the United States, and the number is projected to multiply seven times by 2030 because of the aging, overweight population. Over 90% knee replacements are successful, knee pain goes away and patients become more mobile. In the study, knee replacement surgery and subsequent costs added up to \$57,900 per patient, which was \$20,800 more than was spent on those who did not get the surgery. Those who got artificial knees lived more than a year longer in good health than those who did not, and the researchers calculated the added cost per year of good-quality life at \$18,300. (Losina, 2009) In a 7-year prospective study, patients with severe osteoarthritis who had total knee replacement had significant improvements in health-related quality of life, but health outcomes were negatively influenced by obesity and postdischarge complications, and women typically did not get as much benefit from surgery as do men. Overall, 76.8% were satisfied or very satisfied with their total knee replacement, and 79.5% said they would have the surgery again in similar circumstances. (Núñez, 2009) More than 95% of patients report that they are satisfied with the outcome of their total knee replacement 1 year after surgery. Factors that increased risk for dissatisfaction were younger age, being female, valgus alignment of the knee, and posttraumatic arthritis. (Ayers, 2010)

Unicompartmental knee replacement: Recommended as an option. Unicompartmental knee replacement is effective among patients with knee OA restricted to a single compartment. (Zhang, 2008) In this RCT, the early results demonstrated that the unicompartmental knee replacement (UKR) group had less complications and more rapid rehabilitation than the total knee replacement (TKR) group. At five years there were an equal number of failures in the two groups but the UKR group had more excellent results and a greater range of movement. The 15 years survivorship rate based on revision or failure for any reason was 89.8% for UKR and 78.7% for TKR. The better early results with UKR are maintained at 15 years with no greater failure rate. (Newman, 2009) Long-term studies are needed to appropriately define the role of less invasive unicompartmental surgical approaches. (Borus, 2008) Unicompartmental knee arthroplasty (UKA) and total knee arthroplasty (TKA) are both recommended for

the treatment of medial compartment osteoarthritis in the varus knee. Citing the arduous rehabilitation and bone loss associated with traditional knee arthroplasty, some opt for UKA, especially in young, high-demand patients. (McAllister, 2008) With appropriate patient selection, UKAs are a successful option for patients with osteoarthritis. (Dalury, 2009)

Obesity: After total knee arthroplasty (TKA) for osteoarthritis of the knee, obese patients fare nearly as well as their normal-weight peers. A British research team reports that higher BMI (up to 35) should not be a contraindication to TKA, provided that the patient is sufficiently fit to undergo the short-term rigors of surgery. TKA also halts the decline and maintains physical function in even the oldest age groups (> 75 years). (Cushnaghan, 2008) In this study, the rate of failure of total knee implants, at least up to 5 years after surgery, and the time to failure, were not influenced by patients' BMI, except for subjects affected by morbid obesity, but this group had a small sample size. Based on this evidence, however, it does not appear justified to give low priority to obese subjects for total knee arthroplasty, which would, as a result of restored ability to move, lead to weight loss. (Bordini, 2009) Obese patients presented for and underwent joint replacement surgery at a younger age as compared to nonobese patients. (Gandhi, 2010) Adverse events (eg, perioperative complications, post-op wound infections) occurred in 14.2% of the non-obese, 22.6% of the obese and 35.1% of the morbidly obese patients after total knee replacement. (Dowsey, 2010) A 2-year review of knee and hip replacement surgeries found that complication rates in obese patients were low, supporting doing the procedures even in the heaviest patients, but the review did show that hospital stays were longer in those who were obese than in those who were not. (Parks, 2010) Obese patients may have clinically significant weight loss after total joint arthroplasty, since their osteoarthritis had limited their mobility and ability to exercise. When weight was corrected for natural gain, the overall study population had a trend toward weight loss, and 19.9% of the study population had clinically significant weight loss. (Stets, 2010)

ODG Indications for Surgery -- Knee arthroplasty:

Criteria for **knee joint replacement** (If only **1** compartment is affected, a unicompartmental or partial replacement may be considered. If **2** of the 3 compartments are affected, a total joint replacement is indicated.):

1. Conservative Care: Medications. **AND** (Visco supplementation injections **OR** Steroid injection). **PLUS**
2. Subjective Clinical Findings: Limited range of motion. **AND** Nighttime joint pain. **AND** No pain relief with conservative care. **PLUS**
3. Objective Clinical Findings: Over 50 years of age **AND** Body Mass Index of less than 35, where increased BMI poses elevated risks for post-op complications. **PLUS**
4. Imaging Clinical Findings: Osteoarthritis on: Standing x-ray. **OR** Arthroscopy. (Washington, 2003) (Sheng, 2004) (Saleh, 2002) (Callahan, 1995)

The claimant argues that her BMI, or lack of a calculation thereof, should not be a contraindication for total knee replacement (TKR), since obesity is not a barrier to TKR as it was once thought to be. However, although the ODG does state “. . . that higher BMI (up to 35)

should not be a contraindication to TKA, provided that the patient is sufficiently fit to undergo the short-term rigors of surgery”, the claimant testified that her BMI was 36, and so still in excess of the more lenient standards now contemplated by the ODG. Further, the ODG indicates that where, as here, only one compartment is affected, “a unicompartmental or partial replacement may be considered” as opposed to the TKR procedure requested by Dr. Y, M. D. who requested the preauthorization. The claimant provided no testimony and there was no documentary evidence that the claimant has received any physical therapy since the compensable injury in (year).

Based on a careful review of the evidence presented in the hearing, the claimant failed to meet her burden of overcoming the IRO decision by a preponderance of the evidence-based medicine. The IRO decision in this case is based on the ODG and the evidence revealed that the claimant failed to meet all of the necessary criteria for a total right knee arthroplasty prescribed in the ODG. While the claimant presented some testimony which responded to some of the concerns of the reviewing doctors, she did not present evidence-based medicine to respond to the concerns of the reviewers in regard to a lack of physical therapy, appearing to fall outside the maximum BMI criteria set out in the ODG, or the request for a TKR despite the involvement of only one compartment of her right knee. The preponderance of the evidence-based medicine is not contrary to the decision of the IRO and, consequently, the claimant is not entitled to the proposed total right knee arthroplasty.

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 Workers’ Compensation Division of the Texas Department of Insurance.
 - B. On _____, the claimant was the employee of (Self-Insured), a Self-Insured Employer.
 - C. On _____, the claimant sustained a compensable injury to her right knee.
 - D. The IRO determined that the claimant is not entitled to total right knee arthroplasty.
2. The carrier delivered to the claimant a single document stating the true corporate name of the carrier, and the name and street address of the carrier’s registered agent, which document was admitted into evidence as Hearing Officer’s Exhibit Number 2.
3. A total right knee arthroplasty is not health care reasonably required for the compensable injury of _____.

CONCLUSIONS OF LAW

1. The Workers' Compensation Division of the Texas Department of Insurance 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 a total right knee arthroplasty is not health care reasonably required for the compensable injury of _____.

DECISION

The claimant is not entitled to a total right knee arthroplasty for the compensable injury on _____.

ORDER

The carrier is not liable for the benefits at issue in this hearing. The 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:

CT C S
(STREET ADDRESS)
(CITY), TEXAS (ZIP CODE)

Signed this 1st day of September, 2010.

William M. Routon, II
Hearing Officer