

Prospective Randomized Single-blinded Controlled Clinical Trial of Percutaneous Neuromodulation Pain Therapy Device Versus Sham for the Osteoarthritic Knee: A Pilot Study

Richard W. Kang, MD, MS; Paul B. Lewis, MD, MS; Adam Kramer, ATC; Jennifer K. Hayden, RN, MSN; Brian J. Cole, MD, MBA

This pilot study presents the initial results for a percutaneous neuromodulation pain therapy device (Deepwave) that is associated with no morbidity, good pain relief, and increased function in patients with knee osteoarthritis.

Osteoarthritic pain can be debilitating and lead to significant and undesirable lifestyle changes. Increased emphasis on addressing pain has been fueled by the recent description of pain as the “5th vital sign” by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).¹ Despite efforts to develop new technolo-

gies and methods to treat pain, an “analgesic gap” exists.^{2,3}

Currently, the first step in symptomatic relief includes anti-inflammatory agents such as nonsteroidal anti-inflammatory drugs (NSAIDs) or cyclooxygenase (COX)-selective drugs in conjunction with lifestyle modifications. Often, these measures are not sufficient to completely alleviate the pain, which pushes patients to seek other alternatives such as depot corticosteroid injections, narcotics, and surgery. However, narcotics are capable of producing adverse effects including respiratory depression, sedation, nausea, vomiting, and even behavioral problems.⁴ Corticosteroid injections are more invasive, can only be re-

peated on a limited basis (ie, up to 3 times each year), and have an associated risk of infection and post-steroid flare-up.⁵ For these reasons, other treatment methods are needed to help close the treatment gap and thus reduce patient morbidity.

In addition to pharmacologic treatments, other nonpharmacologic alternatives have been used including acupuncture, cooling, physical therapy, chiropractic manipulation, and

transcutaneous electrical nerve stimulation is justified by the gate control theory, which states that the brain recognizes a limited amount of neural input from a given point in the body at any given moment. This impulse may be superseded by another more powerful and conducive neural input. Although transcutaneous electrical nerve stimulation has been shown to be useful for superficial tissues, it lacks the

Transcutaneous electrical nerve stimulation has been used for 3 decades in a variety of situations to relieve pain.

transcutaneous electrical nerve stimulation. Unfortunately, these alternatives fall short with respect to duration and magnitude of analgesia.

Transcutaneous electrical nerve stimulation has been used for 3 decades in a variety of situations to relieve pain.⁶⁻¹⁴ Using

ability to penetrate into deeper tissue.

A recently developed deep tissue percutaneous neuromodulation pain therapy device, Deepwave (Biowave Corp, Norwalk, Conn), is a viable alternative for narrowing the analgesic gap in treating osteo-

Drs Kang, Lewis, and Cole, Mr Kramer, and Ms Hayden are from the Cartilage Restoration Center at Rush, Rush University Medical Center, Chicago, Ill.

Correspondence should be addressed to: Brian J. Cole, MD, MBA, Departments of Orthopedics & Anatomy and Cell Biology, Cartilage Restoration Center at Rush, Rush University Medical Center, 1725 W Harrison Ave, Ste 1063, Chicago, IL 60612.

