

Zapping Pain: Hot Prospects for the Cold Laser

The latest European import sweeping the American medical community is laser analgesia—a procedure for treating pain with “cold” lasers. Although skeptics have referred to the concept as just so much quackery, a double-blind study was reported last week—reputedly the first such study examining the technique’s efficacy in humans with intractable pain. The report came at a small seminar convened by the Food and Drug Administration’s National Center for Devices and Radiological Health in Rockville, Md. While cautioning that the reported 70 percent success rate needs to be verified by others repeating the technique, seminar coordinator Dave Lytle said that California anesthesiologist Judith Walker’s technique is not only “exciting,” but it also “looks like one of these new techniques that’s going to be very effective.”

Unlike cutting and cauterizing lasers used in surgery, cold lasers (also known as soft lasers) are extremely low-power devices. They do not burn the skin; in fact, patients with their eyes closed cannot even detect when they are being irradiated. According to Lytle, who works in the light-radiation branch of FDA’s division of risk assessment, these lasers use such low power that they appear “not to be harmful at all.” As a result, his agency’s chief concern is determining whether they work as claimed to alleviate pain.

Laser stimulation of nerves is an investigational procedure, and as such has not yet been sanctioned by FDA for routine clinical practice. And in a bizarre but apparently inconsequential twist, the research of Walker and a number of other laser stimulation investigators appears to be technically illegal until officially approved by FDA. Agency officials say such an action can be expected in the near future.

Over the past three years, laser stimulation has been both ballyhooed and ridiculed by the medical-research community—much as acupuncture was 10 years ago. However, the work presented last week by Walker, the director of the Walker Pain Institute in West Los Angeles, Calif., goes a long way toward legitimizing the controversial concept, Lytle told SCIENCE NEWS. He said her study, though small and preliminary, offers some hard data at last on the efficacy of laser analgesia.

In Walker’s study, 26 individuals with afflictions from trigeminal neuralgia (the worst kind of facial pain, she says) to osteoarthritis were each irradiated with light from a one-milliwatt helium-neon laser (having a wavelength of 632 micrometers) that pulsed at a rate of 20 cycles per second. The laser was used to irradiate for 40

seconds each of four sites on each side of the body: a point on the skin overlying the radial and median nerves, respectively (each within two inches of the wrist), and two points overlying the saphenous nerve in the foot (near the big toe and at the heel). Thirty such treatments were administered over a 10-week period. In the control group, the laser’s radiation was targeted at “sham” points—ineffective points that to the untrained eye appeared nearly the same as the active sites.

“We picked these nerves because they innervate the toe, the fingers and the mouth,” Walker says. They also “project through most of the [brain’s] cortex. So by stimulating these three nerves,” Walker says, “we’re actually stimulating 90 to 95 percent of the cortical nerves.” After treatment, each patient was asked to estimate any analgesia on a subjective scale of 1 to 100, with 100 corresponding to total alleviation of pain.

Although many patients experience slight and temporary relief after the first or second treatment, significant and permanent alleviation of pain normally was not observed until after the 30 trials. And sufferers of neuralgia often received additional analgesia from irradiation at the localized source of pain. The patients were followed up six months after the final treatment. Fifteen of the 19 who had benefited from treatment “were pain-free without additional treatment,” Walker says, and “5 of the 7 control subjects who subsequently received irradiation at the nerves were also pain-free for this period. Thus,” she concludes, “laser irradiation can produce long-lasting relief from chronic, intractable pain.”

Though Walker’s data were generally well received at last week’s seminar, the conditions under which she obtained her data were not: Walker’s use of cold lasers on humans was—and still is—against the law.

Because the efficacy of treating pain—or any other medical problem—with cold lasers has not yet been established, FDA law prohibits the commercial sale of these lasers for use on humans. It also prohibits their use in human research unless an “investigational-device exemption”—also known as an IDE—has been issued specifically authorizing use in an approved and properly controlled scientific investigation. IDEs can be issued directly by FDA, or alternatively by an investigational-review board (IRB). Dennis McCarthy of FDA’s standards-and-regulations branch reports his agency has not yet issued an IDE for cold lasers. And although Walker works with a review board, she had not been given reason to believe that she needed to

petition them for an IDE.

Walker first learned of her illegal status in the car on her way to the seminar—and was understandably upset: she told SCIENCE NEWS that she has a memo from her laser’s manufacturer claiming that FDA had approved the device she uses for investigational studies. Because the device had not actually been so approved, she is currently working with FDA and her review board to obtain the needed exemption. But she is far from the only researcher affected; currently there are at least 12 cold-laser experiments underway involving animals or humans, SCIENCE NEWS has learned, and reputedly hundreds of medical practitioners irradiating human patients. According to FDA, only one cold-laser study has received the necessary IDE required to use the device on humans. It’s a trial being conducted by Charles Hennekens of the Harvard Medical School at Brigham and Women’s Hospital in Boston. Like Walker’s, this controlled, double-blind study will look at the laser’s efficacy on pain.

Researchers need not fear prosecution, however. Robert Handren of FDA’s compliance division says the agency is aware that “few of these practitioners willfully took receipt of [a cold laser] knowing that they would be in violation of the law.” In fact, Handren says, FDA is willing to bend over backward to grant formal IDEs for appropriate research; the agency only wishes more researchers knew of the devices’ current questionable status. “Manufacturers have summarily avoided discussing investigational-device requirements,” Handren says. “They’ve put an investigational-device label on the product and then, from our point of view, attempted to circumvent the rest of the regulation. But I think it’s safe to say we’re not going to indefinitely allow them to ignore those responsibilities.”

Joseph Kleinkort, a physical therapist in San Antonio, Tex., is among the pain-therapy community’s leading proponents of cold-laser nerve stimulation. Every weekend he hits the road, training physicians and therapists to use cold lasers. Since first investigating the concept—while consulting to the Surgeon General of the Air Force—Kleinkort has helped promote the military’s adoption of the laser pain therapy. Today, he says, lasers are in use at the Wilfordhall Air Force base and the Walter Reed Army Medical Center in the Washington-D.C. area. Owing to their success with these lasers, representatives of the Army, Navy and Air Force have indicated they would like to discuss with FDA the design of a possible controlled tri-service efficacy trial.

—J. Raloff