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A KNIFE IN THE BACK

Is Surgery the Best Approach to Chronic Back Pain?

By Jerome Groopman

Surgeons have often touted procedures that ultimately proved to be disappointing. In the nineteen-fifties, many patients with angina and coronary-artery disease had an operation that involved tying off an artery that runs under the sternum. The idea was that it would increase the flow of blood to a heart that was being starved of its normal supply. Then, at the end of the decade, a clinical trial demonstrated that patients who underwent a sham operation did just as well as those who had the real one; the placebo effect apparently accounted for the fact that so many patients felt better afterward.

The radical mastectomy, pioneered a century ago, used to be routinely performed, too. Physicians believed that breast cancer spread in a contiguous, stepwise fashion from the primary tumor, and that the only way to eradicate the disease was to remove the entire breast and the underlying muscles. By the nineteen-eighties, it had become clear that tumor cells could spread throughout the body early in the disease, through lymph channels and blood vessels. A lumpectomy, followed by local radiation, proved as effective as a radical mastectomy in treating the cancer, and was far less traumatic to the patient.

Last year, approximately a hundred and fifty thousand lower-lumbar spinal fusions were performed in the United States. The operation, which involves removing lumbar disks and mechanically bracing the vertebrae, is of tremendous benefit to patients with fractured spines or spinal cancers; more frequently, however, it is performed to alleviate chronic lower-back pain. But how effective is it? That's a question that many of the doctors who perform the fusions, and the insurers who pay for them, appear reluctant to ask.

Roughly two-thirds of all Americans will experience significant lower-back pain at least once during their lives; some will also have sciatica, a pain that follows the nerve running from the lower back down the leg. In the United States, current estimates of the cost of medical care for those who have been disabled by severe back pain range from thirty to seventy billion dollars annually. Back pain is most likely to occur between the ages of forty-five and sixty-four, and,

over all, nearly one in four Americans claims to suffer chronically from the problem. Many of these people are being told that fusion surgery is the solution.

Trisha Bryant (her name has been changed) is a former marketing executive in her mid-thirties. Two years ago, while working in a home-furnishings store, she helped a floor manager move some inventory and developed sciatica in her right leg. She continued to work but the pain persisted, and she eventually went to the emergency room for an MRI scan, which showed a small rupture of the disk below the fifth lumbar vertebra. Disks -- the spine's shock absorbers -- are sheathed in a fibrous casing called the annulus, which protects their gelatinous core, and when a disk ruptures bits of it break through the casing. The MRI scan showed that the protruding edge of Trisha's ruptured disk was just touching the right nerve root as it exited the spine. It also showed some narrowing of the disk immediately above -- an early sign of the wear and tear of aging, or "degeneration."

Trisha was given Percocet and told to stop working. For several months, she also received epidural steroid injections, but her discomfort persisted. About nine months after Trisha injured herself, an orthopedic surgeon performed a relatively simple procedure called a discectomy, in which a fragment of the ruptured disk is removed. For more than three-quarters of patients with sciatica who undergo discectomy, the procedure helps relieve pain. Trisha's sciatica went away, but the pain in her lower back increased. Another MRI showed that the disk the surgeon had operated on was protruding again, this time toward both the right and the left nerve roots. The surgeon told Trisha that the next step would be to fuse her lower spine, which had become "unstable." He planned to remove the degenerated disk or disks that were causing the pain and mechanically brace the spine with metal rods and bone grafts. First, however, he wanted Trisha to undergo discography, a procedure that was supposed to determine how much of her pain was coming from the lower protruding disk and how much from the upper, narrowed one. This information would help him decide whether one or two disks should be removed.

Trisha Bryant assumed that the procedures her surgeon recommended were necessary and had been validated by research. I, too, made that assumption when I suffered from recurrent lower-back pain twenty years ago and elected to have a fusion. If Trisha had explored the medical literature, however, she would have discovered that every aspect of her case -- the interpretation of her MRI scan, the diagnosis of spinal instability, the rationale for fusing vertebrae, the impending discography -- was controversial among spine specialists. Indeed, many doctors might recommend that she avoid any further surgery.

For the discography, which was performed at a Boston hospital, Trisha was asked to lie on a long metal table with her lower back exposed. A radiologist trained in the technique explained that he would be applying increasing amounts of pressure to her disks, and that Trisha should try to discern whether the pain she felt during the procedure was "familiar," or "different" from her current symptoms. Then he administered some anesthetic just under the skin and inserted a needle called a trocar into Trisha's lower back. Following his progress on a fluoroscope monitor, he slowly advanced the trocar until it reached the edge of the disk above the ruptured one. He then inserted a fine-gauge needle into the trocar and pushed it into the disk itself. Trisha gasped. "There are lots of nerve fibres in the annulus," the doctor said. "I'm sorry."

He took an instrument resembling a huge syringe which was attached to a digital monitor, fastened it to the fine-gauge needle, and began to press on the plunger. “Now, tell me if you feel any pain,” he said, “and whether the pain you are feeling is the familiar pain that you are suffering from.” If Trisha did not feel her familiar pain, this disk would serve as a control. A series of red neon digits raced across the monitor -- 20, 25, 28, then 30 -- representing the pounds per square inch of pressure that he was applying within the disk; Trisha squirmed with each new increment. At 100, the doctor withdrew the trocar, while the technician recorded her reaction.

The doctor then repeated the procedure an inch or so down Trisha’s spine, on the adjacent disk that was protruding. This time, when the pressure hit 30 on the monitor, Trisha cried, “Oh, God! Oh, God!”

“Is that your familiar pain?” the doctor asked. Trisha said that the pain was viselike, and that she also felt a few electric shocks in her buttocks and her thighs. At 40, Trisha, sobbing, said it was familiar pain.

“It’s over,” the doctor said. He told Trisha that she had done very well.

This radiologist performs discography three hundred times a year. He says that it is his least enjoyable procedure, because patients are intentionally subjected to pain. More troubling, however, is the fact that the results it provides may be dangerously misleading.

Much of the recent research into the limitations of discography as a diagnostic tool was done by Dr. Eugene Carragee, the director of Stanford’s Orthopedic Spine Center, who has received four national prizes in recognition of his work. One study was an assessment of patients who, like Trisha Bryant, underwent discography after having had some form of back surgery. He found that forty per cent of patients who had no back pain after surgery still experienced significant pain during discography; on the other hand, nearly forty per cent of those with persistent back pain after surgery reported no pain during the procedure. In other words, there was no meaningful correlation between pain suffered after surgery and pain suffered during discography.

A related study examined the responses of patients during discography who had other kinds of aches and pains; some of them had somatization disorder, a psychological condition that expresses itself in physical symptoms. Eighty-three per cent of those with somatization disorder experienced significant pain during the procedure. In general, Carragee found that patients who suffered from depression or anxiety were more likely to find discography painful, and some reported lower-back pain for at least a year afterward. For these patients, not only did discography fail to provide clinically useful data but it risked causing long-term pain as well.

CT and MRI scans, which usually precede discography, are often used to make the case for surgery, but the correlation between damaged or degenerated disks and lower-back pain is far from conclusive. A recent study of CT scans showed that twenty-seven per cent of healthy people over the age of forty had a herniated disk, ten per cent had an abnormality of the vertebral

facet joints, and fifty per cent had other anatomical changes that were judged significant. And yet none of these people had nagging back pain. Another study, using MRI scanning, showed that thirty-six per cent of people over sixty had a herniated disk, and some eighty to ninety per cent of them had significant disk degeneration in the form of narrowing or bulging. Given that degenerated disks are often found in people who are fully functioning, it shouldn't be assumed that they are always the cause of the trouble.

If disks aren't necessarily the source of lower-back pain, where else might the pain come from? The various muscles, tendons, bones, joints, and ligaments of the lower back all contain sensory nerves that can transmit messages of pain through the spinal cord and up to the brain; so can organs within the abdomen and the pelvis when they become inflamed or diseased. With so many potential sources of pain, how do doctors arrive at an accurate diagnosis? It turns out that the kinds of diagnostic tests ordered for back patients depend upon the type of physician they consult. A 1994 research study entitled "Who You See Is What You Get" demonstrated that each group of specialists favored the diagnostic tools of their discipline. Neurologists ordered electromyograms (EMGs)—tests in which the integrity of the neural-conduction system is assessed by inserting electric needles into muscles and along nerve tracks. Rheumatologists, who are experts in arthritis and other joint disorders, ordered serologies—blood tests that identify relatively rare autoimmune conditions that affect the spine. And surgeons requested MRI scans, which reveal the anatomy of the disks and vertebral bones and may suggest a surgical solution.

"Each approach to diagnosis and treatment is essentially a franchise, and there are too many franchises battling for control," says Dr. Seth Waldman, who is the chief of the Division of Pain Medicine at New York's Hospital for Special Surgery, a major referral center for bone and joint disorders. "In medicine, if you are able to stick a needle into a person, you are reimbursed at a much better rate by the insurance company. So there is a tremendous drive to perform invasive procedures." Discography is one of them. "At the hospital where I was a fellow training in 1993, discograms were rarely done," Waldman went on. "Over the last few years, they have come into vogue. Surgeons and others order them routinely."

In the end, however, about eighty-five per cent of patients who suffer from lower-back pain cannot be given a precise diagnosis. The pain is usually vaguely attributed to a "strain" or "sprain" in the lumbar region. Whatever the diagnosis, though, the outcomes tend to be similar. In a study that followed patients who consulted their doctors within three days of experiencing acute lower-back pain, ninety per cent improved within two to seven weeks, without specific therapy. Even patients with an acute ruptured disk have a good prognosis, although their recovery is usually slower: some ninety per cent will feel significantly better within six weeks, without surgery. Over time, the disk gradually retracts, so that it is no longer pressing on the nerves, and the inflammation subsides. If you have acute sciatica, discectomy will make you feel better more quickly than you would if you did nothing. But if you have chronic lower-back pain, the case for surgery—particularly fusion—is far more tenuous.

I recently met with a surgeon who performs two or three spinal fusions a week. I will call him Dr. Wheeler. (Like some of the doctors I spoke with, he was concerned that candid answers

would damage his standing in the medical community and reduce patient referrals.) “Spinal instability is routinely given as a diagnosis to these patients with chronic lower-back pain,” Wheeler said. “It is a term used to justify an operation. And it’s a great diagnosis, because it can’t be directly disproved.”

For many years, Wheeler recommended that his patients with back trouble avoid fusion surgery unless it was absolutely necessary. (Fusion *is* clearly recommended when vertebral bones that have been dislocated or damaged by disease are endangering the spinal cord or the nerves.) But there are considerable forces weighing against his conservative advice, particularly when patients have had an accident or an injury on the job, and stand to benefit financially from persistent disability. “In my community, there is a group of neurologists who work directly with lawyers,” Wheeler said. “The lawyers refer the patients to these neurologists after an accident or a work-related injury leaves them with back trouble. The neurologists charge up to fifteen hundred dollars for EMGs, then get five hundred dollars for their report to the attorney. In more than twenty years of practice, I have never seen them read an EMG as negative in an accident case. These patients are then told by the neurologists that they have severe disk disease. This enhances their perception of pain. And if they get operated on they don’t necessarily have to go back to work.”

Wheeler says that he is put in a difficult position whenever one of these referring neurologists tells a patient that tests or scans indicate there is something seriously wrong with his spine. “The neurologist, when challenged, says, ‘I am pro-patient. I am a patient advocate.’ Someone should audit the EMGs that they are doing -- they’re all read as positive, and it’s nonsense.”

Of course, most doctors do not engage in such egregious behavior, and many clinicians believe that they are providing their patients with the best advice available. Nevertheless, the culture of medicine fosters lucrative networks of referrals and procedures which discourage a critical examination of their value. For patients, the system of benefits also favors the trend toward surgery: they generally receive greater disability payments if they undergo back surgery, and higher benefits are paid for fusion operations than for discectomies. Eventually, Wheeler discovered that nearly all the patients he turned away ended up being operated on by other surgeons in his area. If his patients were going to have surgery, he reasoned, he may as well be the one to do it; at least he would know that the operation had been performed competently. Nor could he ignore the fact that, where he practices, the surgeon’s full fee for a simple discectomy is between five and seven thousand dollars, and some twenty to thirty thousand dollars for a fusion.

Dr. Wheeler recently performed a spinal fusion on a forty-five-year-old U.P.S. worker. A year earlier, the patient had injured his back while lifting a package on the job, and although he had followed his doctor’s recommendations, he was still experiencing severe pain. “Something needs to be done,” he told Wheeler. The MRI scan showed disk degeneration, with narrowing and bulging between the fourth and fifth lumbar vertebrae and between the fifth lumbar and the first sacral vertebrae.

The patient was anesthetized and lay on a Jackson table, a large translucent platform that supports the chest and the thighs but allows the abdomen to hang free; this diminishes the pressure on the spinal veins and reduces hemorrhaging. After taking X-rays, Wheeler made a vertical incision some twelve inches long in the patient's lower back, exposing the taut sheath of connective tissue called fascia and the underlying paraspinal muscles. He then used a cutting cautery to burn through the tissues that lie above the spinal column. Acrid smoke wafted up from the patient's back.

"Periosteal elevators," Wheeler said to a resident, who picked up a large metal instrument that resembled a straight spoon with a sharp tip and used it to pull back the bulky muscles surrounding the spine. Wheeler continued with the cutting cautery, and blood flowed into the open wound. Once the muscles had been stripped from the spine, the yellow-white bone of the spinous process -- the protruding ridge of the spine that you feel when you run your hand down your back -- was exposed. Using rongeurs, which look like hedge clippers, Wheeler snipped at the spinous process while the nurse collected the bone chips -- approximately the size of matchsticks -- in a sterile basin. After about twenty minutes of cutting, the dura covering the spinal nerves became visible: a gray-blue tube speckled with blood and slivers of bone.

This was one of the most sensitive points in the operation. A tear in the dura would cause the spinal fluid to leak out, and a surgical slip could permanently damage the spinal nerve. Using a high-speed drill with a very fine bit, Wheeler made holes in the vertebral bones on either side of the spine. "It looks like we are construction workers, not surgeons," he said. He then inserted titanium screws into the holes with a screwdriver.

There are several types of lumbar fusions; Wheeler was performing what is termed a PLIF, a posterior lumbar interbody fusion. After removing the degenerated disks, he would insert bone grafts, which had been harvested from the tibia of a cadaver and customized to fit between the patient's vertebrae. Then the titanium screws and rods would be joined together on each side of the vertebrae, with a connecting rod between them, in the form of an H.

The disk is on the front side of the spinal cord; to expose it, the resident retracted the nerve and the dura. Wheeler was handed a scalpel with a small blade. He gingerly cut into the annulus and, using a curette, scooped out pieces of the disk, which looked like the yellowish gristle at the end of a drumstick. Then, with a fine chisel, he scraped the undersurface of the vertebra; the remaining cartilaginous disk came off with bloody pieces of bone. "You want raw, bleeding bone," Wheeler said to the resident. "It has all sorts of growth factors and substances that facilitate the fusion of the grafts." He then took the cadaver grafts and inserted them snugly between the vertebrae. Wheeler repeated the procedure between the fifth lumbar and the first sacral vertebrae. Now the titanium rods, each of which was five and a half millimetres in diameter and some fifteen centimetres in length, had to be cut to fit the patient's anatomy.

Because more bone is needed to complete a fusion than can be harvested from the spine, Wheeler then used the cautery to tunnel through the patient's right buttock to the crest of the iliac bone. Using an osteotome, a long, thin, chisel-like instrument, he chopped deep into the bone, producing additional chips. "The bone from the iliac crest of the pelvis is potatoes, and what we have from the spinous process of the vertebrae is just the gravy," Wheeler explained.

Wheeler showed the resident how to secure the titanium rods with the screws. A crossbar was then attached, completing the H figure. “Wring out the pads,” Wheeler said to the resident. The resident picked up the blood-soaked gauze and squeezed the liquid into the metal basin that contained the bone chips. The slurry of bone chips and blood was layered along the sides of the titanium rods. Over time, this mixture would solidify, further supporting the spine. Finally, the retractors that held back the paraspinal muscles were ratcheted down, and the muscles and skin were sutured and stapled together. The procedure had taken nearly five hours.

What are this patient’s prospects for a future that is free from back pain? Fairly poor. Dr. Eugene Carragee, at Stanford, performs the operation only on a select group of patients who have been carefully screened. Even so, he estimates that less than a quarter of the operations will be completely successful. For the majority of patients, the surgery does not have a dramatic impact on either their pain or their mobility.

Many patients end up going back to their surgeons; a study of workers injured on the job in the state of Washington who received fusions for degenerative-disk disease reported that twenty-two per cent had further surgery. Dr. Waldman, at New York’s Hospital for Special Surgery, regularly sees spinal-fusion patients who experience persistent pain after multiple operations. Yet few patients facing spinal surgery seem to have any idea that the statistics are so unfavorable, and within the surgical profession itself there’s a curious gap between rhetoric and reality. Last December, the journal *Spine* published the results of an award-winning study from Scandinavia in which patients who underwent fusion surgery for chronic lower-back pain were compared with those who had had no surgery. In this randomized controlled trial, only one out of every six of the patients in the surgical group was rated by an independent observer as having an “excellent” result after two years. It’s a measure of how weak the empirical support for fusion surgery has been that this study is seen as bolstering its legitimacy within the profession.

When you look at the recent history of back surgery, in fact, you can’t help wondering whether many surgeons simply don’t want to subject their practices to rigorous review. In 1993, the federal Agency for Health Care Policy and Research convened a panel of twenty-three experts in back pain from a wide spectrum of disciplines -- neurology, orthopedics, internal medicine, radiology, chiropractic, rheumatology, psychology, nursing. Among its members was Richard Deyo, an internist and an expert on back pain at the University of Washington. Deyo had recently published a statistical analysis of existing research which suggested that spinal fusion generally lacked scientific rationale, and also that it had a significantly higher rate of complication than did discectomy. The panel was to formulate guidelines for the clinical management of acute lower-back pain by evaluating the scientific evidence concerning its diagnosis and treatment. Although the panel did not discuss coverage, it seemed likely that Medicare and private insurers would consider these guidelines when determining reimbursement for different diagnostic and treatment approaches.

Fusion surgery was not explicitly addressed by the panel, since it was considering treatment options for patients only in the first three months after the onset of back pain. Nevertheless, almost as soon as the panel convened, it came under attack. Contending that the

deliberations were not an open process and that the panelists were biased against surgery, a group of spine surgeons, led by Dr. Neil Kahanovitz, an orthopedist who was then a board member of the North American Spine Society, lobbied Congress to cut off A.H.C.P.R.'s funding. Deyo recently told me that the line taken by the opponents of the panel was “ ‘These guys are anti-surgery, they’re anti-fusion.’ But we really had no axe to grind,” he went on. “Our aim was to critically examine the evidence and outcomes of common medical practices.”

After the November, 1994, elections, the lobbyists found the newly configured House of Representatives receptive. “It was the time of Newt Gingrich, and the Contract with America,” Deyo recalled. “Although the American Medical Association, the American College of Physicians, and the American Hospital Association all tried to save the A.H.C.P.R., the House zeroed out its budget.” The lobbying battle moved to the Senate, and though the federal agency ultimately survived, its funds were drastically cut. Sofamor Danek, a company that manufactured hardware used in fusion surgery, sought a court injunction to block publication of the committee’s findings. The guidelines that were eventually published were medically conservative, but the furor surrounding the panel tainted its credibility, and its recommendations have had little impact on surgical practice.

Kahanovitz still defends his earlier actions. But even he admits that he is worried by what he views as a proliferation of spinal fusions. “When I began in spine, there were a handful of fellowships in the country,” Kahanovitz said. “There are now over eighty fellowship programs in spine surgery. That means each year more and more specialists are being trained.” And those specialists, of course, seek opportunities to use their training. The technology, too, has rapidly developed. “We have new toys to play with—all sorts of screws, rods, and cages.” These instruments are aggressively marketed, and generate high profit margins—both for the manufacturers and for the hospitals that use them. At the same time, Kahanovitz said, “We still don’t have a clue where the pain is coming from in the vast majority of chronic sufferers.”

Like most patients who have undergone spinal fusions, I continued to have persistent lower-back pain afterward: I couldn’t run, I couldn’t drive for long stretches, I couldn’t carry heavy grocery bags. When I returned to my surgeon to report on my poor recovery, he offered to perform the operation again. I declined, but I never questioned his medical rationale -- that fusion, although it is a major operation with a high rate of complication, had been my only chance to be free from pain. I simply assumed that I had been very unlucky.

In the past few years, however, reports of other treatment options have begun to circulate. In 1999, the Physicians Neck and Back Clinic, in Minnesota, conducted a study in which sixty patients whose doctors had recommended back surgery agreed to participate in a ten-week program of aggressive strengthening exercises. Forty-six completed the program; thirty-eight of those were available for follow-up, and only three elected to have surgery. The study concluded that many patients who had been told they needed surgery were able to avoid it in the short term by following an exercise regimen, and suggested that doctors needed to reassess their definition of “adequate conservative care” for back pain. Shortly after the study was published, a friend suggested that I attend a similar program at the New England Baptist Spine Center, in Boston.

A first-time visitor to the Baptist Spine Center is greeted by the sight of a large exercise room, full of men and women of all ages engaged in just the sorts of activities that most people who suffer from back pain have been warned against: running on treadmills, lifting weights with their knees, stacking milk crates filled with steel bricks. In addition to the machines that one finds in an ordinary gym, there are specially designed “multihip” machines, back-strengthening machines, and a Roman chair, which braces your lower legs, knee-down, at a forty-degree angle from the floor as you attempt to hold up the rest of your body. Each patient’s level of strength and degree of flexibility are carefully monitored. Records are also kept of the patient’s capacity to execute ordinary activities: pick up a child, sit at a desk, have sexual intercourse. Each patient’s regimen is designed to make the muscles strong again, the ligaments elastic, and the vertebrae well supported.

Dr. James Rainville, who is the head of the Spine Center, explains to his patients that although their pain is debilitating, it is not a sign that they are doing themselves any harm. Like many rehabilitative physicians, he believes that chronic pain originally has a physical cause but that it may become magnified and imprinted along the sensory pathways of the central nervous system. The solution, Rainville thinks, is to try to change the sensitivity of the neurofibres by “reëducating them” through strenuous exercise. In fact, the more the patient exercises correctly, the higher his pain threshold becomes. The hope is that his sensory circuits will be rewired to transmit signals of the healthy aches of exercise rather than the terrifying pain of debility.

Rainville’s program of aggressive rehabilitation exercise has been supported during the past decade by prospective studies. A recent analysis of sixty-seven patients with long-standing back pain, nearly all of whom had had prior surgery or other forms of treatment, showed that the regimen improved physical capacity and reduced pain. Between twenty-five and forty per cent of the patients for whom performing flexion and extension maneuvers was painful when they entered the program were free from pain by the time they were discharged; the others experienced a marked reduction in the intensity of their pain. Still, Rainville argues, it will be impossible to properly compare the results of such nonsurgical interventions with surgery until both options are included in a well-designed randomized study.

Doctors often describe the treatment of lower-back pain as “an industry,” and as long as patients are confronted with an array of conflicting advice, that’s unlikely to change: the desperate patient sitting in the doctor’s office is especially vulnerable to the persuasive recommendations of whatever professional he happens to be consulting. Nine months after meeting Trisha Bryant at the time of her discography, I called her to find out how she was doing. She had undergone fusion surgery in early December. “I’m actually in worse pain now than before the fusion operation,” she told me. “My sciatica has returned.” She has not been able to go back to work, and the pain prevents her from sitting, driving, or walking for extended periods of time. “I’m thirty-five years old,” she said, “and I feel like I have the body of an eighty-year-old.”

Dr. James Weinstein, the head of orthopedic surgery at Dartmouth and a leading expert in back pain, believes that there needs to be a radical improvement in the way doctors approach treatment: patients must be given unbiased information on what is known and not known about back pain and the various ways of treating it. Instead of informed consent, Weinstein advocates

what he calls “informed choice” -- a comprehensive understanding of all the options and their possible risks and benefits.

Weinstein is now leading the first prospective, randomized investigation of discectomy for ruptured lumbar disks to be conducted in nearly thirty years. This trial, which is sponsored by the National Institutes of Health, will cost more than thirteen million dollars. Even so, it will not address fusion surgery for chronic back pain; the participating physicians couldn't agree on diagnostic criteria and forms of treatment. For the tens of thousands of patients facing lower-lumbar fusion each year, no rigorous, government-sponsored study is forthcoming.

In the meantime, Dr. Seth Waldman, who sees the consequences of failed fusions at the Hospital for Special Surgery every week, wishes that the medical profession could be persuaded to show a little restraint. “If you have a screwdriver, everything looks like a screw,” he said. “There will be a lot of people doing the wrong thing for back pain for a long time, until we finally figure it out. I just hope that we don't hurt too many people in the process.”