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## Studies Link Rare Ailment to Pain Pumps

**By [KATIE THOMAS](#)**

When the first cases popped up in orthopedic journals, they read like medical mysteries. Surgeons around the country reported that several active young patients had suddenly developed chondrolysis, a relatively rare ailment in which joint cartilage dies, leaving bone to grind on bone.

Chondrolysis has ended the athletic careers of dozens of high school and college students. In the most severe cases, it has required joint replacements. Many sufferers face lifetimes of pain and disability.

"I've lost so many hours of sleep over this, I can't tell you," said Dr. David S. Bailie, an orthopedic surgeon in Scottsdale, Ariz., who said he had seen dozens of cases of chondrolysis since 2005. "There's nothing worse than a surgeon doing something that causes a problem, not fixes a problem."

Although it is still unknown why chondrolysis develops, several medical studies have concluded that a likely culprit is a pain pump, a postsurgical medical device used to deliver local anesthetics to a specific area through a plastic tube.

Whether the pumps caused the chondrolysis — and whether manufacturers should have done more to warn surgeons about the potential risks — is the subject of more than 150 lawsuits working their way through state and federal courts. Last Friday, an Oregon jury awarded nearly \$5.5 million to a chondrolysis patient, and at least a dozen cases are expected to go to trial this year.

Lawyers for the patients argue that the manufacturers disregarded safety in their quest to expand into the orthopedic market. But the manufacturers and some medical experts argue that more research is needed to determine whether pain pumps are to blame.

Pain pumps became popular with orthopedic surgeons in the late 1990s because they were seen as an alternative to extended hospital stays and safer than prescribing narcotic painkillers. But the [Food and Drug Administration](#) never cleared the pumps for use in joints, and many in the medical profession now say that by exposing cartilage to local anesthetics for up to 72 hours, the devices turned otherwise harmless medications into toxins. In November, the F.D.A. [issued a warning](#) about using pain pumps in joints and ordered manufacturers of local anesthetics and pumps to change labels to discourage doctors from such uses.

Orthopedic surgeons began noticing an increase in chondrolysis diagnoses about [six years ago](#). In most cases, the patients initially seemed to heal normally from shoulder surgery, frequently to repair a torn labrum. Some, like Marcus Suhn, a defensive end for South Dakota State University, returned to practice or

playing. But several months after surgery, their progress slowed or stopped.

“I could make it through 15, 20 minutes of practice, and by that time, my arm was just dead,” said Suhn, who had shoulder surgery in December 2005 and returned to practice in the fall of 2006, his junior year. “I kept saying, ‘Something’s not right there.’ ”

His doctor found that Suhn’s shoulder cartilage had deteriorated, ending his football career. Suhn, now 25, had his shoulder joint replaced in 2008. His pain has lessened, he said, but doctors still do not know the long-term outcome for patients like him.

The recent chondrolysis cases appeared more frequently than usual, said Dr. Constance R. Chu, an orthopedic surgeon and [associate professor at the University of Pittsburgh](#) who studies cartilage regeneration.

“When we see it happen quickly, it’s devastating and you start thinking, why did this happen?” she said.

In late 2006, after a [handful of studies](#) indicated that the pain pumps [might be causing chondrolysis](#), the I-Flow Corporation, the largest pump manufacturer, changed its directions in package inserts to advise doctors to avoid placing the pump catheters in joints. In 2007, I-Flow [posted a bulletin](#) on its Web site notifying physicians of the risk.

The first lawsuits against pain pump companies were filed about two years ago. It is difficult to know the exact number of suits, but I-Flow [reported in November](#) that it was a defendant in 191 chondrolysis cases involving 412 patients. Of those, the company said, 80 suits were dismissed. Kay Jackson, a spokeswoman for the Kimberly-Clark Corporation, which purchased I-Flow last year, declined to comment, citing the pending litigation.

AstraZeneca, which until 2006 sold a local anesthetic that was used in the pumps, is a defendant in 68 active cases, said Tony Jewell, a company spokesman. AstraZeneca did not promote the drug, bupivacaine, for use in pain pumps inserted in the joint, nor did it seek approval for such a use, he said.

Jewell added, “We intend to vigorously defend ourselves in this matter.”

Lawyers for the chondrolysis patients say the pain pump makers were slow to react to evidence that their devices were dangerous.

“It’s a failure-to-warn case,” said Jeff Gibson, whose Indianapolis firm is handling about 50 pain pump cases. “Instead of warning the public, they hid the information.”

Pain pump makers saw orthopedics as a potentially lucrative market for their devices. In 1998, McKinley Medical, a manufacturer, asked the F.D.A. for permission to revise its labeling to indicate that the pumps could be inserted in joints; the agency refused because it said no previous devices had proved such a use to be safe.

The F.D.A. said in its November warning that it had never cleared pain pumps to infuse local anesthetics in joints. Even so, doctors are permitted to use devices in an “off label” fashion. Bailie, the Scottsdale surgeon,

said the labeling was too vague.

“There was nothing on the package insert to say, ‘Do not use in the joint,’ ” he said. Bailie published a case series on chondrolysis in 2009.

Lawyers for the companies deny that the pain pumps were marketed for use in joints. They have also questioned whether the pumps caused chondrolysis, noting that some cases developed in patients who had never used one.

“The plaintiffs have these allegations,” said Frederick H. Fern, the national coordinating counsel for the manufacturers McKinley and Curlin, which is owned by Moog. “These allegations have not been scientifically proven by any valid scientific methodology.”

Even researchers who think pain pumps are a cause of chondrolysis say more proof is needed.

“There’s no study that I’m aware of that shows a direct cause,” said Chu, who conducted several laboratory studies that found local anesthetics could kill cartilage cells.

Of her own research, she said, “I think it provides important information, but it’s a huge leap to say this is what’s going on in the patient.”

In June, a federal district court judge in Florida dismissed a case against the pump manufacturer Breg, citing a lack of scientific proof. Most of the pending cases are in the discovery phase, said Laura B. Kalur, a lawyer in Portland, Ore., who is handling about 70 cases.

Kalur said about half her clients are former athletes.

“The saddest part is that these are usually Type A, very motivated, active people that this happens to,” she said. “It is degenerative. It will never get better.”

One of Kalur’s clients is Whitney Moore, who played junior varsity soccer at [West Virginia University](#) and later opened a strength and conditioning business for young athletes. In 2004, after injuring her shoulder playing recreational soccer, she had surgery and developed chondrolysis.

Moore said she had to close her business, and her life has changed in many small ways. For example, Moore said, on a recent night out she had to ask a friend to help her cut the crust on her key lime pie.

“Until this injury, I was in pretty prime physical condition,” Moore said. “It’s a whole flip of my world.”

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