

# Weighing the Risks of a New Implanted Device



Scott Fedor's life changed in the shadow of a second in July 2009. He plunged into Coldwater Lake a successful, physically fit, happily married 33-year-old executive. He emerged a quadriplegic whose life would be redirected and redefined by his injury.

Scott's story is all too familiar to people with spinal cord injuries: a long hospital stay, slow rehabilitation, set backs, relapses, frustration, fear, depression, anxiety.

Despite the challenges he continues to face, Scott remains hopeful. Much of that hope, he says, comes from his experience with clinical trials.

## Starting Over

After his accident and a two-week hospital stay in Michigan, Scott was flown to MetroHealth Medical Center in Cleveland which he calls the "epicenter of spinal cord research" in Ohio.

It was during his stay at Metro, several months into his recovery, that Scott met another quadriplegic who was demonstrating a new technology called a spinal cough assist system. The device, which was in clinical trials, is designed to generate a cough in spinal cord patients whose abdominal muscles are paralyzed.

The inability to cough is a major problem for patients with spinal

injuries. Because they are unable to clear secretions from their lungs, patients must be suctioned via a trach tube. The need for suctioning dramatically limits their independence – they must always travel with a suction kit and someone trained to use it – and presents a potentially life-threatening risk. Pneumonia is the second leading cause of death among quadriplegics.

At the time, Scott's lungs, which were badly damaged during his accident, were being suctioned as many as six times a day. Still, he says, the trial technology didn't impress him. He didn't think the woman performing the demonstration appeared terribly healthy and she wasn't using the device very effectively.

Scott desperately wanted to live his life without being suctioned and wanted the trach tube removed, as it posed an infection risk. What's more, he knew from personal experience the potential benefits of implanted devices. Months earlier he'd had a diaphragm pacing system implanted that had enabled him to breathe without a ventilator. Still, he wasn't convinced this new technology held much promise.

"What I'd read on paper about the device wasn't what I saw during the demonstration that day. I remember asking myself, 'Is this worth having my spine cut open for?'" Scott told his doctors he was still undecided.

A few weeks later, Scott had reason to reconsider his decision when his doctors introduced him to a second patient who had been implanted with the cough assist system. The young man, whose story and injury mirrored Scott's, "looked to be in really good health," Scott recalls. "He came in and showed me this really forceful cough. It was night and day between him and the demonstration with the other woman."

Scott's interest was piqued. "I started asking a lot of questions," he says. Researchers noted that there were a number of explanations that might account for the discrepancy in the two patients' coughs, including the device setting, the patients' age and the extent of muscle atrophy. "Until you have the surgery and test the device a few months after it's implanted, there's really no way of knowing how your body is going to react to it," Scott says.

Scott faced a tough decision. Only 13 people had been implanted with the device so far. Three of them were dead, one as the result of a septic reaction from an infection due to not keeping the implant site clean.

## Weighing the Risks

Scott considered the risks. He'd have to be on a ventilator during the six-hour surgery, an inherently risky proposition for a cord patient. There was a danger Scott's muscles might atrophy during the procedure

and he'd spend the rest of his life on a ventilator. To complicate matters, researchers were preparing to test a new version of the technology. If Scott wanted to participate in the trial, he would have to agree to remain anesthetized for an extra hour so doctors could test the wiring that would be used in the next generation of the device.

Finally, Scott says, he had to wrestle with a deeply personal fear. "I was nervous about becoming the bionic man," he says. "I still had a strong belief that my body would repair itself. I didn't want to turn myself into a part robot. I wanted my body to remain as whole and uncompromised as possible."

As time went by, Scott's abdominal muscles weakened and his lungs had to be suctioned with increasing frequency. Ultimately, Scott decided the independence and enhanced quality of life the cough assist system promised justified the risks.

"I decided: if I can do things now to help give me more independence and help restore me, why not? Yes, there are risks, but my life expectancy goes up if I can clear my secretions."

In September 2010, Scott underwent a grueling surgery that lasted nearly eight hours. A surgeon made an incision in the middle of his back and drilled into his T9, T11 and L1 vertebrae. A small electrode was placed on the dura mater surrounding his spinal cord and connected via a wire to a receiver on Scott's abdominal muscles. To stimulate a cough, an external receiver that was not attached to the body would be held against Scott's abdomen where the internal receiver was located. Pushing a button on the external receiver would send a charge to the spinal cord nerves that would



**Scott Fedor**

trigger the abdominal muscles to contract, forcing a cough.

The surgery went well and Scott was taken off the ventilator without incident, but he had to wait several weeks to learn whether or not the surgery had worked.

Scott can still remember the day when he was finally allowed to test the device. "I was making jokes, but I was a little apprehensive," he says. "The doctors were telling me I'd have to learn to time the cough with the jolt. Since I didn't know what it was going to feel like, I wasn't sure what that was going to mean."

His initial reaction upon being shocked was relief: it didn't hurt. Still, he says the sensation was strange. Because he didn't have his timing down, it felt "like swallowing a really big hiccup." After a few tries, Scott's timing improved and he was able to produce a very productive cough.

"To me it was a really powerful sound that I hadn't made in a long time," he recalls.

After a few weeks of practice, Scott began to experience the benefits of the surgery. Soon he was able to clear his secretions and, by December

2010, he was able to have his trach removed.

"That was a life changer," he says. "A big hope of mine was realized."

### The Road Ahead

Today, nearly a year after the surgery, Scott continues to do well. He regularly demonstrates the cough assist device for other spinal cord patients and says he continues to discover new, secondary benefits. He recently learned to use it to stimulate a sneeze.

His experience has been so positive he hopes to be selected for a second trial. Doctors at Metro hope eventually to conduct a trial of a functional electronic stimulation (FES) bicep implant. Scott is undergoing preliminary assessments and hopes he will be a candidate for the procedure when the time comes.

Although he's working on developing a new career as a motivational speaker, Scott's not a Pollyanna. He's frank about what his injury has cost him: his physical body, marriage and financial independence.

Still, he's optimistic about the future. He knows that trials have risks and that they often don't realize their objectives. But, he's willing to keep trying. "I think there's a lot to be said about having a positive mental attitude," he says. "In a trial you have to go into it saying, 'This is a chance – if it works – to get some independence back in my life.'"

*This story is from a series of articles created by CISCRP as part of their educational awareness campaign to increase public understanding that those who volunteer to participate in clinical trials are genuine "Medical Heroes."*