

Public Abstract:

Spinal cord injury (SCI) affects over 250,000 people in the United States with 12,000 new cases occurring each year. It is a devastating injury resulting in either temporary or permanent loss of ability to move or feel the arms and legs, loss of ability to control bowel and bladder function, and paralysis in general. If the injury is classified as complete, meaning there is no movement or feeling or control of bowel or bladder function below the level of injury, then the chances of such people recovering function are less than 10% at 1 year.¹ While much has been discovered about how SCI results in loss of function, little beyond physical therapy and rehabilitation has been able to offer hope in the ability to stand or walk in patients who are paralyzed from the chest on down. In fact, even at model SCI centers across the United States, the improvement in ability to move went up only 16% from the time of admission to a model SCI rehab facility (mean ASIA motor score of 46.5) to time of discharge (mean score of 54.0), and reached only 17% at a year out from rehab (mean score 54.9).² This implies that *restoration of standing and walking in completely paralyzed individuals (ASIA A category) is unlikely to change at least a year following care even at a national model SCI center.*

Yet, animal research in the past 15 years by scientists and engineers (Dr. Mushahwar and others) have shown that restoration of standing and walking can occur if the lower half of the spinal cord circuitry is preserved following the injury. Examples of cats who are completely paralyzed in the lower half of the body have been able to stand and walk over ground using a new method of micro-stimulation of the lower spinal cord. The reason this is possible is because of the fact that neuronal circuits exist in the lower spinal cord that contain the coded instructions for either standing or walking, much like a computer controls much of our modern day vehicles. As long as these circuits remain intact following an injury, it is possible in animals to restore standing or walking by reactivating these circuits through precise control of hair-like, micro-wires inserted into the spinal cord. As few as 16 of these wires can establish this in the animals studied by Dr. Mushahwar. We believe that such exciting technology can be offered to humans with similar types of injury. However, to date this has not been proven possible in completely paralyzed people with intact circuitry of the lower spinal cord. In order to determine whether this technology is even feasible in humans, we must first determine the existence of the same types of circuitry in these individuals as exists in the animals tested so far. This requires some individuals who have a complete spinal cord injury and are undergoing spine surgery for other reasons, to **volunteer** to have these small wires temporarily inserted in the lower spinal cord to prove this concept.

We are asking for two volunteers with complete spinal cord injury (T2-T8 level of injury) and evidence of a normal spinal circuitry below the injury apply for this novel technology study. Although the micro-wire implants will only be temporarily inserted into the cord for research purposes, the results of this research will potentially offer hope to all spinal cord injury people. We wish to establish the concept of this technology in 2 volunteers with complete paralysis from an injury in the thoracic region from T2-T8 who are in need of spine surgery in the region of the lower thoracic region for other reasons. During the surgery, we are asking for an additional amount of time (up to 2 hours) where we can test the idea of micro-stimulation of the lower spinal cord to create leg movement similar to standing and walking. While **there are no immediate benefits to either volunteer in this study**, positive findings of this study should be apparent immediately upon test stimulation within the surgery. If so, we feel these findings would lead to new technology developments within a 10 year period that would likely benefit the two volunteers as well as many others. The risks of this study would be the potential for infection, spinal fluid leak, discomfort from the procedure, and failure to show any proof that such circuitry exists to restore standing or walking in humans through these concepts. Each volunteer would be observed for 6 months following the ISMS testing for signs of these problems.

¹ National Spinal Cord Injury Statistical Center, University of Alabama at Birmingham, 2010 Annual Statistical report. Tables 61 is based upon over 5100 records of SCI patients admitted into a model care center since October 31, 2000.

² National Spinal Cord Injury Statistical Center, University of Alabama at Birmingham, 2010 Annual Statistical report. Tables 66 and 67 are based upon 4606 records since October 1993.

We are particularly sensitive to the need for improved rehabilitation solutions in SCI individuals that have been injured in OIF/OEF campaigns. Our strategy offers a novel, ground breaking study that will likely lead to a new generation of medical devices to restore standing and gait in SCI military service members and veterans.