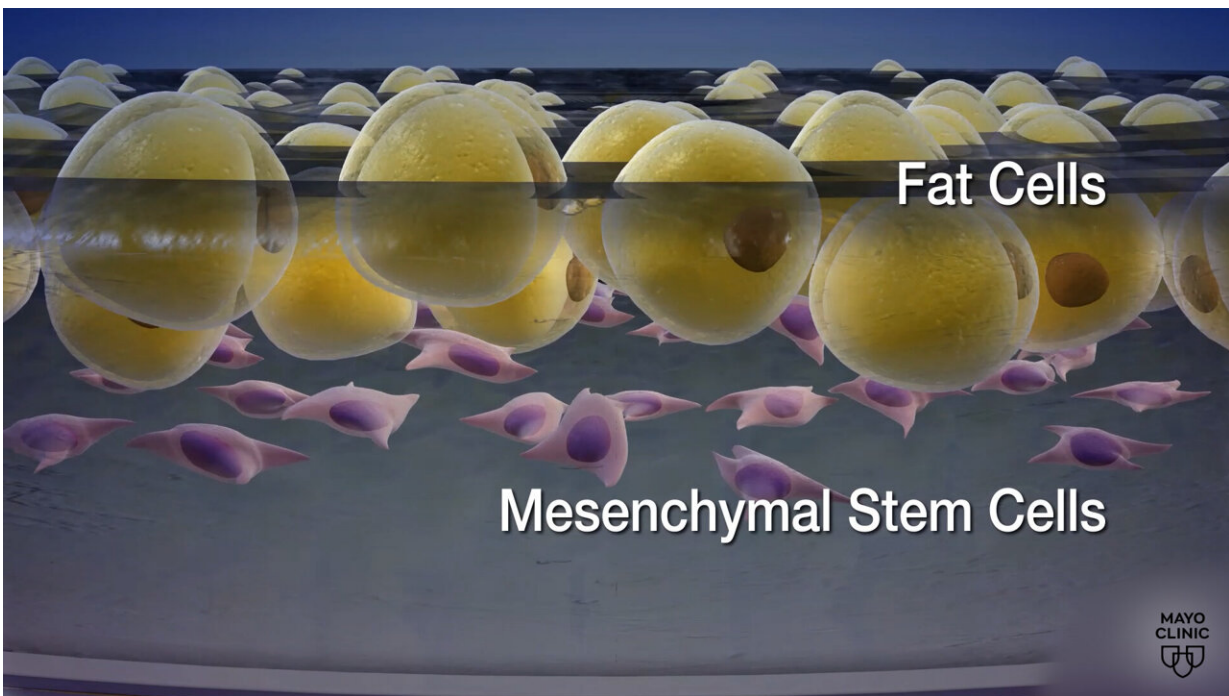


# Study documents safety, improvements from stem cell therapy after spinal cord injury

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Stem cells. Credit: Mayo Clinic

A Mayo Clinic study shows stem cells derived from patients' own fat are safe and may improve sensation and movement after traumatic spinal cord injuries. The findings from the Phase I clinical trial appear in *Nature Communications*. The results of this early research offer insights into the potential of cell therapy for people living with spinal cord injuries and paralysis for whom options to improve function are

extremely limited.

In the study of 10 adults, the research team noted seven participants demonstrated improvements based on the American Spinal Injury Association (ASIA) Impairment Scale. Improvements included increased sensation when tested with pinprick and light touch, increased strength in muscle motor groups, and recovery of voluntary anal contraction, which aids in bowel function.

The scale has five levels, ranging from complete loss of function to normal function. The seven participants who improved each moved up at least one level on the ASIA scale. Three patients in the study had no response, meaning they did not improve but did not get worse.

"This study documents the safety and potential benefit of stem cells and regenerative medicine," says Mohamad Bydon, M.D., a Mayo Clinic neurosurgeon and first author of the study.

"Spinal cord injury is a complex condition. Future research may show whether stem cells in combination with other therapies could be part of a new paradigm of treatment to improve outcomes for patients."

No [serious adverse events](#) were reported after stem cell treatment. The most commonly reported side effects were headache and musculoskeletal pain that resolved with over-the-counter treatment.

In addition to evaluating safety, this Phase I clinical trial had a secondary outcome of assessing changes in motor and sensory function. The authors note that motor and sensory results are to be interpreted with caution given limits of Phase I trials. Additional research is underway among a larger group of participants to further assess risks and benefits.

The full data on the 10 patients follows a 2019 [case report](#) that

highlighted the experience of the first study participant who demonstrated significant improvement in motor and sensory function.

## **Stem cells' mechanism of action not fully understood**

In the multidisciplinary clinical trial, participants had [spinal cord injuries](#) from motor vehicle accidents, falls and other causes. Six had neck injuries; four had back injuries. Participants ranged in age from 18 to 65.

Participants' stem cells were collected by taking a small amount of fat from a 1- to 2-inch incision in the abdomen or thigh. Over four weeks, the cells were expanded in the laboratory to 100 million cells and then injected into the patients' lumbar spine in the lower back. Over two years, each study participant was evaluated at Mayo Clinic 10 times.

Although it is understood that stem cells move toward areas of inflammation—in this case the location of the spinal cord injury—the cells' mechanism of interacting with the spinal cord is not fully understood, Dr. Bydon says.

As part of the study, researchers analyzed changes in participants' MRIs and cerebrospinal fluid as well as in responses to pain, pressure and other sensation. The investigators are looking for clues to identify injury processes at a cellular level and avenues for potential regeneration and healing.

The spinal cord has limited ability to repair its cells or make new ones. Patients typically experience most of their recovery in the first six to 12 months after injuries occur. Improvement generally stops 12 to 24 months after injury.

One unexpected outcome of the trial was that two patients with cervical

spine injuries of the neck received stem cells 22 months after their injuries and improved one level on the ASIA scale after treatment. Two of three patients with complete injuries of the thoracic spine—meaning they had no feeling or movement below their injury between the base of the neck and mid-back—moved up two ASIA levels after treatment.

Each regained some sensation and some control of movement below the level of injury. Based on researchers' understanding of traumatic thoracic spinal cord injury, only 5% of people with a complete injury would be expected to regain any feeling or movement.

"In spinal cord injury, even a mild improvement can make a significant difference in that patient's quality of life," Dr. Bydon says.

## **Research continues into stem cells for spinal cord injuries**

Stem cells are used mainly in research in the U.S., and fat-derived stem cell treatment for spinal cord injury is considered experimental by the Food and Drug Administration.

Between 250,000 and 500,000 people worldwide suffer a spinal cord injury each year, according to the [World Health Organization](#).

An important next step is assessing the effectiveness of stem cell therapies and subsets of patients who would most benefit, Dr. Bydon says. Research is continuing with a larger, controlled trial that randomly assigns patients to receive either the stem cell treatment or a placebo without [stem cells](#).

"For years, treatment of spinal cord injury has been limited to supportive care, more specifically stabilization surgery and physical therapy," Dr.

Bydon says.

"Many historical textbooks state that this condition does not improve. In recent years, we have seen findings from the medical and scientific community that challenge prior assumptions. This research is a step forward toward the ultimate goal of improving treatments for patients."

**More information:** Mohamad Bydon et al, Intrathecal delivery of adipose-derived mesenchymal stem cells in traumatic spinal cord injury: Phase I trial, *Nature Communications* (2024). DOI: 10.1038/s41467-024-46259-y , [doi.org/10.1038/s41467-024-46259-y](https://doi.org/10.1038/s41467-024-46259-y)

Provided by Mayo Clinic

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