## StemCels & Regenerative Medicine Congress

## Groundbreaking stem cells surgery and a potential treatment for ALS

A compilation of articles exploring Ted Harada's miracle treatment



#### The potential of stem cells in the treatment of ALS

Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. Motor neurons reach from the brain to the spinal cord and from the spinal cord to the muscles throughout the body. The progressive degeneration of the motor neurons in ALS eventually leads to death. When the motor neurons die, the ability of the brain to initiate and control muscle movement is lost. With voluntary muscle action progressively affected, patients in the later stages of the disease may become totally paralyzed.

It is becoming evident that it is not only the motor neuron that is at risk in ALS but the neighboring cells as well. Attempts to replace these cells are ongoing and may be more feasible than motor neuron replacement. Stem cells are vehicles to help remaining cells survive. This, together with other alternative infusion and treatments, are being explored by researchers.

As the first ALS patient to be successfully treated with stem cells, Ted Harada has a unique perspective of the potential of stem cell therapeutics. His experience speaks for itself, which is why we are featuring a collection of articles and videos published on the topic of his unexpected ALS miracle. Furthermore, you can hear Ted presenting a patient testimony at Stem Cells & Regenerative Medicine Congress on September 30<sup>th</sup> at the Hyatt Regency in Cambridge, MA.

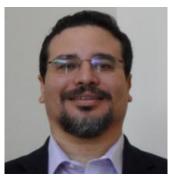


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#### **About Ted Harada**



I am 41 years old, and have been married to Michelle Harada for 18 years. We have 3 wonderful children together, son and 2 daughters, Teddy – 14, Jordan 12 and Ashleigh 9. I'm a former Managing Director for FedEx Ground and I also worked at DHL as a Director of Operations and a Regional Manager for Shred – It, secure document services. Michelle and I are originally from Lancaster, PA and currently reside in McDonough, Georgia where we have lived for the last 7 years. In August of 2010 I was diagnosed with ALS by Dr. Williams of Peachtree Neurology. Later the second opinion was confirmed by Dr. Jonathan Glass, Director of the ALS Clinic at Emory University.

Soon after my diagnosis, I was informed about the Neuralstem stem cell trial being conducted at

Emory University in conjunction with the U of Michigan and Dr. Feldman. As I explained to Dr. Boulis (Neurosurgeon at Emory University) and Dr. Glass clear, who made it abundantly clear that this trial was not designed to help me, when I decided to participate in the trial there were 3 main reasons I wanted to participate. 1) I am not a do nothing person and of every option I researched stem cells and this trial seemed to be the most cutting edge option out there for an ALS treatment. 2) There was a real sense of altruism to me to have the opportunity to be part of something bigger. As I told them someone has to be the first astronauts and if I could help future ALS patients that truly motivated me and I felt an obligation to be part of the long term solution. 3) While I do not personally play the lottery as they say you cannot win if you do not play.

I had my first stem cell surgery and injections on March 9th 2011. I received 10 injections into the grey matter of the lumbar region of my spinal cord, totaling 1 million stem cells. On August 22, 2012 I was fortunate to have been 1 of 3 people chosen to have a second surgery and injections of stem cells. This time I received 500,000 stem cells through 5 injections into my cervical spinal cord. I have also (not required as part of this trial) volunteered to have a spinal tap every quarter so they can look for bio markers and potentially learn how I was helped.

I am very passionate about the advocacy work I do on behalf of the ALS Association as well as education people about stem cells. I am on the Board of Directors of the Georgia Chapter of the ALS Association; where I serve as the co – chair of the Public Policy Committee and the Chair of the Patient Services Committee. I have lobbied for ALS patients both at the Georgia State Capitol as well as in Washington D.C. I have been very fortunate and extremely blessed to have been the beneficiary of these cutting edge treatments. I feel a true obligation to provide hope to others in the ALS community and to educate the public about ALS and the need for more research and funding.



#### Give hope to those with ALS

Originally published in The Atlanta Journal-Constitution and written by Ted himself, this article is a powerful exploration of the feeling of hopelessness upon being diagnosed with ALS, and the subsequent glimmer of hope upon receiving the successful neural stem cell transplant that helped turn around Ted's symptoms.

"I have a lot to live for: a beautiful family, friends and a life I love. Until a few short years ago, I also had hope. All that changed in an instant. My future, my career, my hope of watching my three children grow up, attending their graduations, walking my daughters down the aisle, holding my grandchildren and growing old with my wife — all of that disappeared with two short sentences: "I'm sorry, you have ALS. There is no cure.""

Continue reading the full article here.



### Henry County man undergoes experimental ALS stem cell surgery

Originally reported by FOX 5 Atlanta, this story explores how Ted "has gambled on a risky, cutting-edge spinal surgery not once, but twice."

The story goes on to discuss the process of the stem cell transplant into the spinal cord, results from Ted's first transplant, and then the decision to go back for round two.

"Nothing is promised, nothing guaranteed. But there's hope. And for the Haradas that's enough."

Continue reading the full story and watch the video segment here.



#### **ALS: Living with mortality**

Originally reported by the Detroit Free Press, this is a great video to take a look at!

It really puts a face to the ALS experience, by exploring feelings of mortality upon diagnosis, by addressing emotions felt by the patients – Ted Harada and fellow ALS clinical trial patient, Ed Tessaro – as well as their wives as their partners through this journey.

The story also provides some interesting behind-the-scenes footage from the clinical trial and surgery itself.

In Ted's words from this video, "I know how the book ends if I do nothing. So I'm trying to rewrite the ending, to add a few more chapters at the very least."

Watch the video here.



#### After Geron, stem cells' new saviors

Originally published by The Daily Beast, and written by Sharon Begley, this article discusses the termination of Geron's clinical trial program to treat spinal-cord injuries with stem cells, and the subsequent hope to be found in other potential stem cell treatments.

The article briefly looks at Advanced Cell Technology, and their clinical stem cells trials for the treatment of blindness (notable because Catholic nuns were among the patients, even though the Vatican has condemned stem-cell research).

And it takes a more in-depth look at Neuralstem's ALS clinical trial, exploring embryonic stem cells vs. neural stem cells, the process of the stem cells transplant, the goals of the clinical trial, and the somewhat unexpected signs of improvement found in Ted Harada following the surgery.

Read the full article here.



#### Patient, doctors encouraged by ALS trial

Originally reported by CNN, this article explores Ted's ALS trial, including perspectives from Dr. Jonathan Glass, who oversaw the clinical trial at Emory, Dr. Eva Feldman, who designed the clinical trial at Emory, and Dr. Nicholas Boulis, who invented the surgical procedure used to inject the stem cells.

At the start of the trial, Dr. Glass and Dr. Boulis "explained to patients that participation in the trial would not cure or even benefit them personally, but it would help doctors learn more about how to treat ALS in the future. The first phase of any clinical trial is to prove that a treatment won't injure patients, not that the treatment works. The first part of the ALS study... is designed to show that the surgical procedure to inject the stem cells into the spine is safe, and that the patients' bodies won't reject them."

Initial trial results suggested that the cells did not harm any of the 12 patients in the Emory study, nor did they accelerate the progression of their ALS. So with the initial goals of the trial to prove that the treatment wouldn't injure patients, this in itself was a sign of success.

Ted's improvements were an unexpected but pleasant addition. "He realizes he hasn't been cured, but it's like his clock has been set back, he says."

Read the full article here.



#### Stem cell research could lead to ALS cure

Originally reported by CBS 2 New York, this video takes a look at ALS, and interviews both Dr. Jonathan Glass and Dr. Nicholas Boulis, who were involved in the clinical trial at Emory.

The video defines Ted as "the one that actually got better!"

Watch the video here.



#### ALS patient is living his second miracle

Originally published by Crain's Detroit Business, and written by Tom Henderson, this article explores how Ted is living his second miracle, following his second successful stem cells transplant.

According to Ted, as quoted in this article, "The first time, it's easy to say it was an outlier. Luck. But I've been helped twice. Twice, and you can throw luck out the window. They've got to figure out, now, what's going on with me," he says. "We've got to turn Lou Gehrig's disease into Lou Gehrig's chronic illness."

The article touches on the feelings of disbelief following Ted's first surgery. The worry that he was experiencing the placebo effect rather than actual improvement. And then subsequent hope following a second round of successful stem cell transplantation.

Read the full article here.



### We'd love to meet you too...

Ted will be speaking on his experience at Stem Cells & Regenerative Medicine Congress 2013.

You will also hear insights from the FDA, industry and academia and how each stakeholder will contribute to the advancement of cell therapies.

Hear from pharma, biotechs, academia and government as they discuss:

- How to optimize clinical development of stem cell therapies
- How to overcome strategic and regulatory challenges
- How to negotiate reimbursement
- How to navigate funding and partnership opportunities
- How to implement stem cell platforms into drug discovery

Interested in attending or sponsoring? Contact me, Andre, at +1 646 619 1797 or email me at andre.singer@terrapinn.com for more information .



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