**////Title: The walk2Wellness Trial: Measuring the Impact of a Wearable Sensory Prosthesis on People with Peripheral Neuropathy**

**////Stand-first**:

Dr Lars Oddsson [LAHRS ODS-ON], CTO of RxFunction and Adjunct Professor at the University of Minnesota is co-inventor of a wearable device called Walkasins® to help improve balance and reduce the risk of falls in people with sensory peripheral neuropathy. The walk2Wellness trial incorporated five clinical sites where they demonstrated that by replacing sensory stimulation for balance, this prosthetic device can have a positive impact on clinical mobility outcomes and quality of life for those who have suffered nerve damage causing loss of sensation in their feet.

**////Body text:**

Sensory peripheral [PUH RIF UH RUHL] neuropathy [NYUH ROP UH THEE] is a medical condition that occurs when the nerves which send messages to the brain relating to temperature, pain and sensations of touch have been damaged. Common causes are diabetes and medical treatments like chemotherapy as well as unknown factors.

Sensory peripheral neuropathy frequently causes numbness in the feet which is associated with poor balance and coordination, and a high risk of falling. Not only are falls a source of fear and mental distress for the individual involved, they can also cause severe injury and physical trauma. After a fall there may also be longer-term mental and physical effects, as well as an increased likelihood of further fall incidents.

One study found that 65% of older individuals with peripheral neuropathy experienced at least one fall over the course of a year and 30% reported an injury from a fall. Another impact of this condition is a reduction in walking speed, an important indicator of health. Clinicians commonly view walking speed as a ‘6th vital sign’ and a predictor of life span. Although walking speed naturally reduces with age, the decline may be up to four times greater for those who have a loss of sensation in the feet.

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Despite the negative impact sensory peripheral neuropathy has on balance and mobility, treatments and interventions remain limited to walking aids and balance exercises. Studies have shown that balance exercises can be effective if done correctly and on a regular basis, while research on strength and endurance exercises has not demonstrated the same level of positive impact. None of the currently available interventions target the root cause of the problem with balance – the lack of sensation in the feet.

In response to the need for a solution to the lost nerve function, Dr Lars Oddsson co-developed Walkasins® Lower Limb Sensory Prosthesis. Walkasins aims to replace foot sensations and provide balance information to the brain in people with sensory peripheral neuropathy leading to improved balance and gait.

This prosthetic device is worn externally and includes a leg unit worn around the ankle connected to a sensor instrumented footpad placed in the shoe. When the foot creates pressure on the footpad during standing and walking activities, a microprocessor running a sophisticated algorithm contained in the leg unit triggers low-intensity balance stimuli emitted from the leg unit in four different locations to signal events related to the wearer’s state of balance.

The device has different modes for standing and walking. In standing mode, the Walkasins® signals when foot pressure starts to drift from the balance position. During the walking mode, the leg unit signals the heel contact with the ground and when the toes leave the ground. Dr Oddsson and his team expect that Walkasins® can help to improve walking and balance in those suffering from sensory peripheral neuropathy and decrease their risk of falls.

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To determine the impact of daily long-term use of this prosthetic device, the team of researchers and clinicians from five different sites conducted a clinical trial called walk2Wellness. The trial investigated the effectiveness of Walkasins® through a range of clinically validated gait and balance measures, and some patient-reported experiences. Forty-five participants aged 21 to 90 years old completed the 10-week trial. All participants had a formal medical diagnosis of sensory peripheral neuropathy along with documented issues with balance and mobility. All participants met the criteria for high fall risk according to the commonly used Functional Gait Assessment measure and had a sufficient level of mobility to take part in the trial.

Performance measurements were taken before the trial and at weeks 2, 6 and 10. These included tests of balance and gait function, quality of life, physical activity, social participation, pain and fall rates. Participants were permitted to use walking aids during the trial period but were asked not to engage in any balance training, so that the effects of Walkasins® could be evaluated in isolation from other influences. The prosthetic device was fitted on both legs and those taking part were encouraged to continue normal levels of activity both indoors and outdoors.

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The trial was a success, demonstrating clear improvements in walking and balance performance leading to a reduction in fall risk following the use of Walkasins®. As part of the trial, participants underwent testing to check if their sensory peripheral neuropathy had changed during the 10 weeks. No change was detected across any of the participants, meaning that any improvements in performance can be attributed to Walkasins®.

Overall, the average (mean) fall risk was reduced and for 13 participants, this improvement was returned all the way to normal levels. Both regular and fast walking speeds also notably improved. In addition, participants improved their performance on the Timed Up and Go test. This is a standard test that requires participants to stand up from a seated position, walk 10 feet, turn around, then walk back to the chair and sit down.

The participants were also analysed for those who had fallen in the 6 months prior to the trial and those who had not. Encouragingly, improvement was shown across both groups but more so for those who’d had a recent fall who showed a decrease in the number of clinical factors related to fall risk. While the trial had some limitations, such as no control or placebo group, it would be difficult to create an environment where the participant isn’t aware that they are using an active prosthetic device, especially when the aim is to help improve walking and balance.

The trial findings show the potential for the Walkasins prosthetic device to have a great impact in helping people with sensory peripheral neuropathy lead safer and more active lives.

This SciPod is a summary of the paper ‘The Effects of a Wearable Sensory Prosthesis on Gait and Balance Function After 10 Weeks of Use in Persons With Peripheral Neuropathy and High Fall Risk – The walk2Wellness Trial’, from Frontiers in Aging Neuroscience. DOI: https://doi.org/10.3389/fnagi.2020.592751.

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