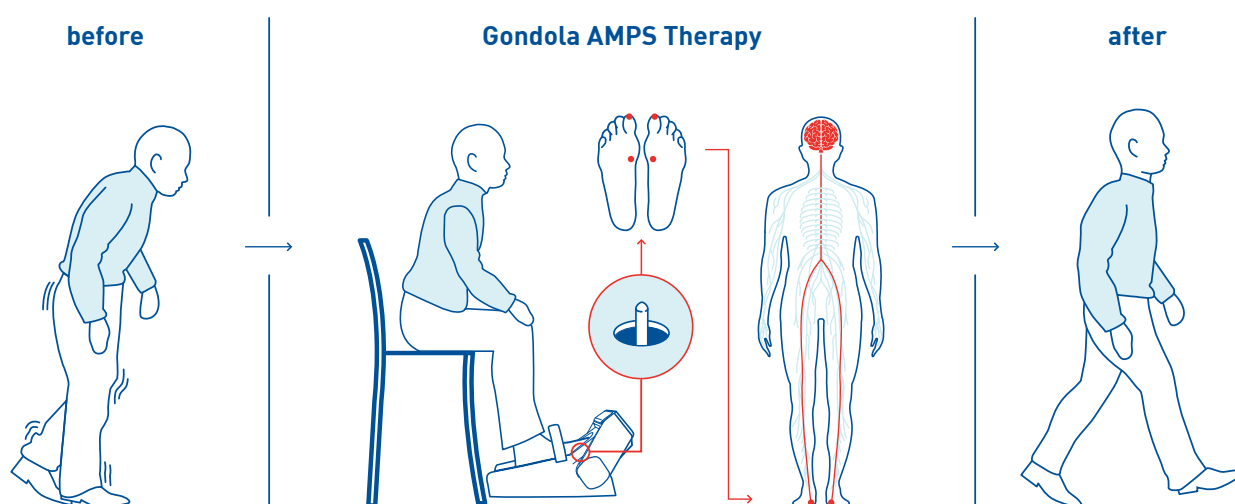




AMPS therapy in Parkinson's disease

a treatment for walking and balance impairments



TREATMENT IN PARKINSON'S DISEASE (PD)

Symptoms associated with Parkinson's disease (PD) are often managed with dopaminergic and dopamine agonist pharmaceutical therapies, which aim to increase or mimic dopamine in the brain¹. While these therapies can be useful for specific PD movement symptoms such as tremor and rigidity, they are often unsuccessful in treating gait, posture, and balance symptoms, especially in the intermediate and advanced stages of PD². For example, freezing of gait is not usually well-managed with dopaminergic therapies, and freezing of gait can even be induced with dopamine agonist therapies². Therefore, there is an unmet need in PD treatment options for gait and balance disturbances.

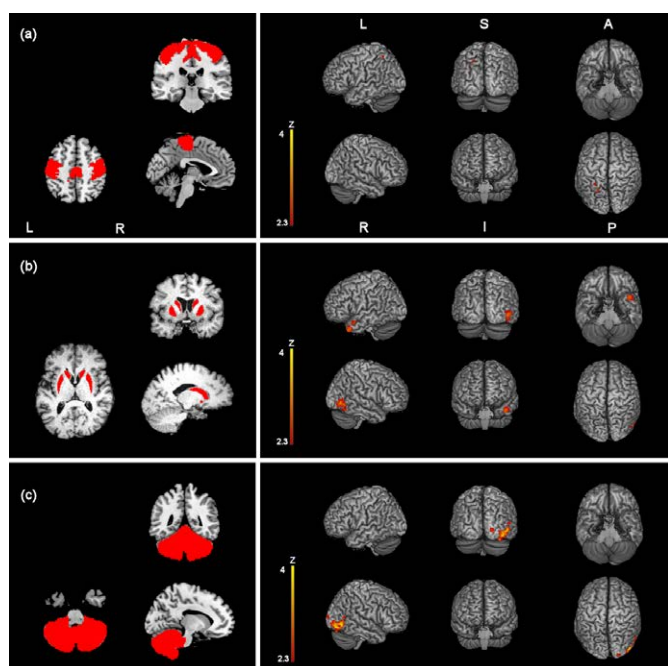
AMPS THERAPY

Automated Mechanical Peripheral Stimulation (AMPS) is a novel therapy approach with robust scientific evidence supporting its efficacy in treating gait and balance difficulties in PD patients. With AMPS therapy, pressure pulses are delivered at two specific locations on each foot by means of the Gondola® medical device.

The stimulation time is relatively short, taking less than two minutes to complete the designated four rounds of stimulation at each of the locations on the feet, and treatment is only necessary two or three times per week to maintain long-term benefits.

THERAPY RESULTS

The safety and efficacy of the AMPS therapy as delivered using the Gondola® medical device have been documented in 12 clinical research studies of over 230 PD patients. These studies, primarily randomized sham-controlled trials, indicate that AMPS therapy results in increased walking speed³⁻¹⁰, faster timed up-and-go (TUG)⁴, increased stride length³⁻¹⁰, more symmetrical gait^{3,9}, and improved turning capabilities^{3,4}, signifying improvements in dynamic balance¹¹. The beneficial effects are apparent after a single AMPS therapy and can remain up to ten days afterwards⁵. Furthermore, the walking improvements from AMPS therapy have been corroborated in both the ON³ and OFF⁴⁻¹⁰ medication conditions in PD patients with or without freezing or shuffling of gait symptoms^{7,8,10}.



Source: Quattrocchi CC, de Pandis MF, Piervincenzi C, Galli M, Melgari JM, Salomone G, et al. (2015) Acute Modulation of Brain Connectivity in Parkinson Disease after Automatic Mechanical Peripheral Stimulation: A Pilot Study. PLoS ONE 10(10): e0137977. doi:10.1371/journal.pone.0137977

MECHANISM OF ACTION

The mechanism believed to be associated with AMPS is an induced synaptic plasticity with strengthening of the neural circuits involved in walking automaticity. This hypothesis is supported by the clinical outcomes³⁻¹⁰, the discovery of increased connectivity between brain regions involved in walking control^{12,13}, and an increase in brain-derived neurotrophic factor (BDNF) after AMPS⁸. BDNF is an essential regulator of synaptic plasticity, supporting motor learning¹⁴. This reinforcement of the neural network might lead to reinforced walking automaticity. Indeed, after AMPS, dual-task performance while walking is also improved⁹. This result highlights that executive control is decreased after AMPS and thus walking automaticity is improved, supporting the hypothesized mechanism of action.

RELIEF OF PD RELATED ISSUES

In addition to improvements in motor control, AMPS therapy can have beneficial systemic effects in PD patients. Studies of cardiovascular modulation indicate that the AMPS therapy can

significantly reduce resting blood pressure and improve the cardiovascular system's ability to react and maintain constant blood pressure¹⁶. Furthermore, the autonomic regulation of blood pressure in response to postural changes (standing) was improved after a single AMPS therapy³. Therefore, AMPS therapy can provide a complementary gait rehabilitation therapy that also relieves common PD-related cardiovascular issues.

GONDOLA® MEDICAL DEVICE

While the Gondola® medical device (CE marked and FDA Break-through Device Designation) yields positive results in the majority of PD patients, individual treatment responses must be verified with a Gondola-trained therapist. To ensure that stimulations are delivered at the proper locations of the feet, a **personalized Gondola® Home Device** is configured for each patient for use at home. Alternatively, in a medical multi-patient setting, a single Gondola® Professional Device can be quickly adapted by a trained operator for each patient. The Gondola AMPS treatment is intended to be a complementary treatment in addition to pharmaceutical and/or deep-brain stimulation (DBS) therapies. As such, the Gondola AMPS treatment provides a means of managing a broader range of PD symptoms, giving patients the opportunity for improved quality of life and greater independence.



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CONTACT

Gondola Medical Technologies SA
Route de la Corniche 4
1066 Epalinges - Switzerland
Email: info@gondola-medical.com
Headquarters: +41 91 921 38 38

