

Path Finder for freezing of gait in people with Parkinson's disease

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is Path Finder laser shoe attachment. It is used as a walking aid and is designed to help prevent freezing of gait in people with Parkinson's disease.
- The **innovative aspects** are that it is currently the only hands-free visual-cueing device for people with Parkinson's disease available in the UK.
- The intended **place in therapy** would be in place of other visual-cue walking aids but together with a reduced number of physiotherapy sessions, depending on the individuals' disease stage and personal preference. It would be used by the patient in their home or in the physiotherapy clinic. It may also be used in physiotherapy as a training tool for people with early stages of Parkinson's disease.

- The **main points from the evidence** summarised in this briefing are from 1 case report and 2 observational pilot studies involving a total of 21 adults with Parkinson's disease and freezing of gait symptoms. They show that Path Finder has the potential to reduce freezing of gait and the risk of falls in patients with Parkinson's disease.
- **Key uncertainties** around the evidence or technology are that available evidence is limited in quantity and quality, based on a small number of patients and lacking in evidence from an NHS healthcare setting.
- The **cost** of Path Finder is £395 per unit (exclusive of VAT). The **resource impact** would be an additional upfront cost to current practice. However, the use of the technology may be resource releasing if it can reduce the incidence of falls and emergency visits.

The technology

Path Finder (Walk With Path Ltd.) is a laser shoe attachment designed to prevent freezing of gait in people with Parkinson's disease. The device is mounted on a strap that is attached to each shoe. It works by projecting a green laser line in front of the opposing foot, providing a visual obstacle over which the user should aim to step. By providing a visual cue, the device aims to trigger walking by focusing the attention of the wearer. The lasers are activated by each step and provide continuous cueing while walking. Path Finder operates on a rechargeable battery and the company recommend users charge the unit daily.

Innovations

Path Finder is the only hands-free, visual-cueing device currently available in the UK for people with Parkinson's disease. Agilitas was also identified as a hand-free, visual-cueing aid; however, this device is not yet available in the UK. Alternative visual-cue walking aids exist but all depend on the use of either a cane or walking frame, which are not necessarily needed by all people with Parkinson's disease. The hands-free aspect of Path Finder is designed to reduce complexity for the user by minimising the need for multi-tasking.

Current care pathway

NICE's guideline on [Parkinson's disease in adults](#) recommends starting treatment with

levodopa, a dopamine agonist or a monoamine oxidase (MAO-B) inhibitor depending on the effect of symptoms on quality of life, as well as the person's individual circumstances, treatment preferences, needs and goals. A dopamine agonist, MAO-B inhibitor or catechol-O-methyl transferase (COMT) inhibitor may be considered as add-on therapy to levodopa when symptoms are not well controlled by levodopa alone. Deep brain stimulation is an option for people with advanced Parkinson's disease whose symptoms are not well enough controlled by best medical therapy. Impaired gait and postural instability are the leading causes of falls and disability in Parkinson's disease. Symptoms can become increasingly problematic as the condition progresses and may not be improved with pharmacological intervention. Non-pharmaceutical interventions such as physiotherapy can help improve function and maintain independence for patients, by correcting and improving posture, balance and general mobility. People with early stages of the disease may also be referred to a physiotherapist for assessment, education and advice about maintaining physical activity. People with Parkinson's disease and impaired gait may choose to use walking aids such as a cane or frame, with or without visual-cue technology.

Population, setting and intended user

Use of Path Finder is intended to reduce freezing of gait episodes and time spent freezing in people with Parkinson's disease. Around 1 in 350 people are affected by Parkinson's disease with an estimated 145,000 people in the UK with the condition ([Parkinson's UK, 2018](#)). It is estimated that freezing of gait symptoms may affect around 40% of these people. Path Finder is likely to be used in place of other visual-cue walking aids but with a reduced number of physiotherapy sessions; this will be dependent on the patient's disease stage and individual preferences. The PD-REHAB study ([Clarke et al. 2016](#)) states that 4 58-minute physiotherapy and occupational therapy sessions over an 8-week period is reflective of standard NHS practice. The technology will be started by a physiotherapist but may also be recommended by a neurologist. Path Finder is intended to be used by patients at home or in the physiotherapy clinic. It can also be used as a training tool in the clinic for people with early stages of Parkinson's disease.

Costs

Technology costs

The company state a wholesale price of £395 per unit (excluding VAT).

Costs of standard care

Alternative treatment options to Path Finder in the UK include other walking aids, such as LaserCane and U-step walker, and physiotherapy sessions. The associated costs for each of these is summarised in table 1.

Table 1 Cost of standard care

| Description | Cost | Additional information |
|----------------------------------|----------------------------------|--|
| LaserCane | £225 | Walking stick with visual-cue technology. |
| U-step 2 with laser/audio module | £795 | Walking frame with visual-cue technology. |
| Physiotherapy | Costs of services vary across UK | After applying a unit cost per contact time, Gumber et al. (2017) estimated the mean annual cost to the NHS as £24.72 per person with Parkinson's disease. |

Resource consequences

If adopted, the technology has the potential to reduce the number of falls caused by freezing of gait among users, resulting in a decrease in associated healthcare costs and resources. The company claim the use of the device may have the potential to help to increase activity levels and reduce the number of physiotherapy sessions in users, as well the number of emergency department visits, all of which would have the potential to contribute to further cost savings. There is no available evidence that supports these claims. According to [Gumber et al. \(2017\)](#), the estimated mean annual cost of ambulance and emergency department services is £95.37 per patient with Parkinson's disease. No changes in facilities or infrastructure will be needed to adopt the technology, and a small amount of basic training on how to use the device would be needed. Training is provided by the company or their distributor free of charge in the form of visits, demonstrations and online video content. The technology is not yet widely used in the NHS but is available in 2 private physiotherapy clinics, as well as for small-scale testing by neurologists at 1 UK NHS centre.

Regulatory information

Path Finder is a CE-marked class I medical device.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Parkinson's disease predominantly affects older people and is more common in men than women; both age and sex are protected characteristics. Under the Equality Act, many people with Parkinson's disease may be protected under the disability element of the Equality Act because their condition is likely to have long-term adverse effects on their ability to do normal day-to-day activities.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

One case report and 2 observational pilot studies including a total of 21 people with Parkinson's disease and freezing of gait symptoms are summarised in this briefing. [Table 2](#) summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The preliminary evidence from the 2 included pilot studies suggests that Path Finder has the potential to reduce freezing of gait and the risk of falls in patients with Parkinson's disease. However, available evidence for the benefits of Path Finder in the NHS is limited by the low quality of relatively small studies all from outside of the UK from a single centre, so there is no comparative study to NHS standard practice. Also, there are no published comparative studies on the use of the technology compared with other visual-cueing devices which may be replaced by this device. Additional outcomes, such as the effect of the technology on the number of falls caused by freezing of gait and associated emergency visits, the number of physiotherapy sessions and patients' overall quality of life, could provide information on the long-term benefits of the technology for both the patient and healthcare system.

Table 2 Summary of selected studies

| <u>Barthel et al. (2018a)</u> | |
|---------------------------------|---|
| Study size, design and location | Observational before-and-after study involving 21 people with Parkinson's disease and a recent history of regular and disabling freezing of gait, done in a controlled gait laboratory in the Netherlands. |
| Intervention and comparator(s) | Intervention: Path Finder laser shoe. No comparator. |
| Key outcomes | 2 patients were excluded from the analysis; 1 for inability to see the laser and 1 because freezing of gait episodes could not be quantified. The use of Path Finder was associated with statistically significant reductions in the number of freezing of gait episodes, both 'off' (45.9% reduction; p=0.007) and 'on' (37.7% reduction; p=0.028) medication. Path Finder reduced the percentage of time spent frozen by 56.5% 'off' medication (p=0.004) and by 51.4% 'on' medication (not significant; p=0.075). Path Finder resulted in a small increase in double arm support time when in the 'on' medication phase. No significant changes were seen in any of the other the gait measures recorded using accelerometry. None of the patients reported worsening of their gait and most subjectively reported positive experiences. |

| | |
|---------------------------------|---|
| Strengths and limitations | Study was a non-UK pilot study with a small number of patients and no comparator. The study did not take into consideration previous experience of patients with cueing, the assessor was not blinded to the cueing condition and the study was limited by the lack of adjustment for multiple comparisons in post hoc analyses. It was done in a controlled gait laboratory, so results may not be generalisable to the home setting. |
| <u>Barthel et al. (2018b)</u> | |
| Study size, design and location | Open-label before-and-after pilot study involving the same 21 people with Parkinson's disease and severe freezing of gait from Barthel et al. (2018a), done in a home setting in the Netherlands. |
| Intervention and comparator(s) | Intervention: Path Finder laser shoe. No comparator. |
| Key outcomes | Path Finder was associated with statistically significant improvements in freezing of gait severity ($p=0.036$), with no correlation with cognitive status (Frontal Assessment Battery). The technology was associated with a 41%, 58% and 31% reduction in self-reported falls, near falls and freezing of gait episodes, respectively. Patients reported positive subjective experiences on the efficacy of the technology. |
| Strengths and limitations | The study was done in a home setting, providing evidence in a real-world environment. It was done over a period of 3 weeks, involving a baseline week (wearing the device but without cueing), a test week and a follow-up week (without device). No patient demographics or information on the level of compliance was provided and there was limited information methodology. The lack of a passive or active control means the effect of a placebo effect cannot be ruled out. |
| <u>Ferraye et al. (2016)</u> | |
| Study size, design and location | Case report of a 79-year-old man with 12-year history of Parkinson's disease and clinical presentation that includes severe freezing of gait and falls. |
| Intervention and comparator(s) | Intervention: Path Finder laser shoe. No comparator. |

| | |
|---------------------------|--|
| Key outcomes | Video evidence from this case report showed that use of the technology while the user was taking chronic dopaminergic medication helped normalise gait pattern and reduce freezing in the patient. This improvement extended to the home setting where the patient was allowed to use the technology for 1 week. |
| Strengths and limitations | This case report provides low-level evidence and reported outcomes are from 1 patient only, lacking generalisability. No quantitative measures were made. The first author designed and developed the technology. |

Recent and ongoing studies

No ongoing or in-development trials were identified.

Specialist commentator comments

Comments on this technology were invited from clinical experts working in the field. The comments received are individual opinions and do not represent NICE's view.

All of the specialist commentators were familiar with laser technology for the treatment of freezing of gait and 2 of the 7 specialists had used Path Finder before.

Level of innovation

Most of the commentators noted that the use of a laser to provide a visual cue is not a novel concept, but the hands-free design of Path Finder is the technology's main innovation. Two commentators noted that Path Finder was a minor variation to standard care because of this. Laser canes and walkers were identified as comparable technologies by commentators, neither of which are hands-free. Agilitas was identified as a comparable hands-free wearable technology by 3 commentators, all of whom noted that this Australian device is not currently available in the UK. It uses a laser attached to a belt and 1 commentator added that it uses a flashing dot as a cue rather than a laser line. Auditory metronomes were also mentioned by 3 commentators as alternative non-laser, hands-free cueing devices.

Potential patient impact

Less frequent freezing of gait episodes and subsequent reduction in the risk of falls were identified as potential benefits to patients. Improved quality of life and increased confidence in walking, as well as helping to maintain mobility and independence for longer and assisting in rehabilitation of admitted patients, were other potential benefits noted by commentators. The hands-free nature of the device was noted as a patient benefit by 2 commentators and the relative ease of use of the device by 1 other. Some commentators thought that the technology could have the potential to lead to reduced hospital admissions, earlier discharge from rehabilitation, fewer medication changes and reduced need for physiotherapy and occupational therapy sessions. However, most noted that these benefits are speculative because of the lack of available evidence. One of the commentators did not believe the technology would lead to a change in the current care pathway or clinical outcomes. People with Parkinson's disease who do not need walking aids but have freezing of gait were identified by 3 commentators as individuals who would particularly benefit from the technology. Those with substantial freezing of gait symptoms that do not respond to standard medical therapy were also identified by 2 commentators. Two of the commentators thought that the technology could potentially benefit those with atypical Parkinson's disease or vascular gait disorders in whom freezing of gait symptoms may be present.

Potential system impact

The potential to reduce physiotherapy needs, as well as the number of falls, fractures and the healthcare costs associated were system benefits identified by some of the commentators. One commentator felt that the technology is unlikely to have a major effect on the healthcare system and another did not feel it would reduce routine outpatient physiotherapy sessions unless the technology was able to reduce the incidence of falls. One commentator noted that its use as a training tool in physiotherapy is likely to be limited because there is often a poor carry-over effect when use is stopped. The same commentator did not think it would have a major effect on physiotherapy times and costs, because patients with freezing are typically only seen once or twice as an outpatient. One commentator thought it would cost the same as standard care, while 3 commentators agreed that adopting the technology would be cost incurring in the short term. One of these commentators noted that the cost of Path Finder was comparable to other cueing devices and another added that the cost of Path Finder was relatively small when compared with the total treatment costs for a person with Parkinson's disease. All other commentators felt that, without good evidence to show the reduction in falls, the cost

impact of the technology was uncertain. Six commentators thought the technology would be an addition to standard of care, while 1 thought the device would replace the laser cane for those that did not need a walking aid. Most commentators agreed that there would be little resource impact apart from the cost needed to buy the device, and no extra staff or other equipment would be needed to adopt this technology. Four commentators did not think that training would be needed, while 3 felt that some level of training would be needed.

General comments

Most commentators noted that Path Finder is not yet widely used in the NHS, but were not aware of any major barriers to adoption other than cost and lack of good quality evidence. None of the commentators were aware of any safety issues however, 1 commentator noted a potential risk of worsening gait freezing if patients were distracted by the attached device and were not able to concentrate fully on the laser line. Specialists highlighted that patients with poor dexterity or eyesight may have difficulty using the device, and may need some level of support. One commentator felt that the technology may only have benefits for indoor use, as the laser line may be harder to see in bright outdoor light. Specialists noted the huge variation in current physiotherapy provision across the UK, and 1 commentator felt that Path Finder may play a role in empowering physiotherapists in understanding the difference physiotherapy can make for people with Parkinson's disease. It was also noted that if the same device was to be used by multiple people, healthcare professionals would need to consider infection control measures. All commentators highlighted the need for further research in a larger cohort of patients. Commentators felt that long-term data (6 to 12 months) from randomised controlled trials and real-world studies were needed to address key uncertainties around the benefits of the technology, in particular whether a reduction in freezing of gait with Path Finder is associated with a decrease in falls, improved quality of life and cost-savings.

Patient organisation comments

Parkinson's UK noted that patients with freezing of gait are at a higher risk of falls, and that falls are the largest cause of emergency hospital admissions in people with Parkinson's disease. Also, freezing of gait can cause anxiety because the person may not be aware of the trigger, making symptoms unpredictable. This can reduce their confidence in staying active or leaving the house, and many fear they may freeze in dangerous situations such as in the middle of the road. People with Parkinson's disease can feel

misunderstood, and their movements are often misinterpreted. Those with freezing of gait have expressed the increased stress of being in public because of the reactions of others. Parkinson's UK noted that Path Finder may reduce freezing of gait and the risk of falls, and that this could improve the quality of life of patients and provide cost-savings for the NHS. They also thought Path Finder would provide particular benefit to those with freezing of gait symptoms who do not respond well to other freezing management techniques (such as auditory cues, sensory cues or vibrational cues). Feedback from their patients and professionals (a physiotherapist and an occupational therapist with expertise in Parkinson's disease) is that the device is non-discrete and bulky. Patients felt it drew attention to them, and were uncomfortable wearing it. Based on this, Parkinson's UK felt the technology would only be suitable for those with extreme freezing symptoms and no sense of embarrassment. Overall, their patients did not find Path Finder easy to use and noted difficulties with attaching the device, particularly to certain shoe types such as slippers and canvas shoes. Patients felt that more information is needed on how to attach and operate the device correctly. It was also noted that the device appeared to work better on hard flat surfaces such as tiled or wooden floors and that the laser lines were difficult to see outdoors in daylight. Parkinson's UK noted that the device is costly and in its current form does not meet the needs of patients.

Specialist commentators

The following clinicians contributed to this briefing:

- Carl Counsell, honorary consultant neurologist and clinical reader, NHS Grampian and University of Aberdeen, did not declare any interests.
- Jan Adriaan Coebergh, consultant neurologist with special interests in movement disorders, cognitive neurology and functional symptoms. St Georges Healthcare Clinicians, given 3 pairs of Walkwithpath shoes to trial (2017 to ongoing).
- Dr Lucy Strens, consultant neurologist, University Hospitals Coventry and Warwickshire NHS Trust, did not declare any interests.
- Dr Jane Alty, consultant neurologist, Leeds Teaching Hospitals NHS Trust, shareholder in ClearSky Medical Diagnostics (2016 to ongoing), member of advisory boards for Abbvie and Merz, paid training facilitator for Allergan; part of a team that won an international award from Hummies (prize money) for work on Parkinson's dyskinesia; sponsorship to attend medical conferences from Ipsen Ltd, UCB, Bial, Britannia, Medtronic, AbbVie.

- Dr Yen Tai, consultant neurologist, Imperial College NHS Trust, involved in research on wearable devices to monitor gait freezing (2015 to ongoing), has been loaned a Path Finder device by the company to trial (2016 to ongoing).
- Dr Richard Genever, consultant physician and geriatrician, Chesterfield Royal Hospital NHS Foundation Trust, did not declare any interests.
- Dr Jane Noble, consultant geriatrician, Newcastle upon Tyne Hospitals NHS Foundation Trust, did not declare any interests.

Representatives from the following patient organisations contributed to this briefing:

- Parkinson's UK.

Development of this briefing

This briefing was developed by NICE. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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