USER TESTING OF CUE[1] DEVICE WITH STAPP ONE INSOLE SENSOR TECHNOLOGY

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Prepared by Charco Neurotech

Abstract

Charco's user testing for the CUE[1] device was carried out with Stapp one insole technology in a joint UK-Austria collaboration. Data was collected of 5 participants with Parkinson's disease showing gait-related symptoms. Objective features to assess gait in Parkinson's disease (peak heel pressure, double support time and gait symmetry) were extracted. Results indicated that participants made promising improvements in gait whilst using the CUE[1] device, with 100% of participants improving in at least one feature.

1. Introduction

1.1 CUE[1]

Since Professor Charcot first noticed the benefit of vibration on people with Parkinson's in the 19th century, the scientific community has developed a deeper understanding of how movement is controlled neurologically, including the role of sensory input and how this goes wrong in Parkinson's.

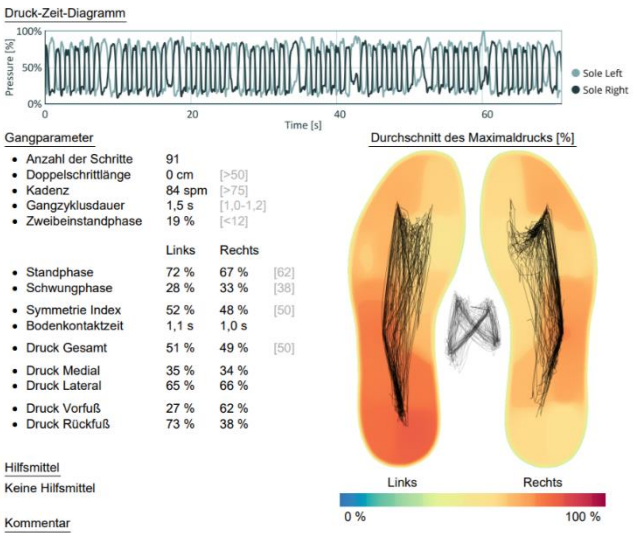
Current research indicates that vibrotactile stimulation may counter-act the movement symptoms seen in Parkinson's [1][2], leading to the potential for better quality of life for those suffering from the disease. CUE[1] uses the science of vibrotactile stimulation through a non-invasive wearable device that sits on the sternum, relieving Parkinson's movement symptoms like slowness and stiffness. The vibrations are produced in a specialised pattern developed through extensive research and testing with people with Parkinson's.

Through the pattern's wave shape and frequency, the device delivers two scientifically validated non-invasive Parkinson's therapies in a combination unique to this device; focused stimulation and cueing [3]. While the precise mechanisms by which these therapies work to improve movement symptoms in Parkinson's is not completely understood, the scientific literature as well as our own user testing demonstrates their efficacy.

Previous user testing provided promising insights into the benefits of CUE[1]. Users had an average time improvement of 16% when using the device across several different tasks designed to assess stiffness and slowness. Participant's subjective experience also greatly improved, claiming that their movement was 'smoother', 'better co-ordinated', and 'under more control'. In this report, an attempt is made to lay the groundwork for using objective measurements to assess changes in gait-related symptoms while using CUE[1]. This was done with the aid of technology provided by Stapp one.

1.2 Stapp one

Stapp one's device is a sensor-based shoe insole, which measures movements relatively with a combination of pressure sensors and Inertial Movement Unit (IMU) sensors. The 12 integrated pressure sensors allow for spatiotemporal pressure calculations, whilst the IMU sensors measure the acceleration as a function of time. Data can be analysed through Stapp one's proprietary software, where automatic analysis reports can be generated, or exported in CSV format. Figure 1 shows an example reported generated by Stapp one's software.



1.3 Literature

Examples of the use of sensor-based insoles in the context of Parkinson's disease can be found extensively in literature. Previous studies have attempted with varying success to extract objective gait-related features that can both correlate with symptom severity and discriminate between People with Parkinson's (PwP) and healthy individuals. Successful studies have seen a significant correlative reduction in walking velocity [4][5], stride length [4][6][12] and peak heel pressure [7][8][9][10], and an increase in double support time (the proportion of time during walking that both feet are on the ground) [11][12] and gait asymmetry [13][14] for gait-disturbance in Parkinson's.

2. Methods, Results & Discussion

2.1 Methods

6 participants with Parkinson's disease were recruited for the joint Charco-Stapp one user testing. All participants were volunteers and provided consent and signed waiver forms. The experiment was done in a non-clinical setting. The widely accepted symptom assessment system, MDS Unified Parkinson's Disease Rating, was used to assess symptoms with and without CUE[1]. Testers completed a Timed-Up-and-Go (TuG) 3m test for both conditions whilst wearing a Stapp one insole. 1 participant was removed from the study for scoring normal gait on the pre-device UPDRS assessment. With the remaining five participants and the use of Stapp one's technology, the mean of the peak medial heel pressure, the double support time and the gait symmetry were then calculated from the insole data.

2.2 Results

The peak medial heel pressure for each participant and foot is plotted in Figure 2, while the double support time and UPDRS scores are plotted in Figure 3, and the gait symmetry is plotted in Figure 4. Figure 2 shows unanimous improvement in the medial peak heel pressure of the right foot and 3 out of 5 participants demonstrating improvement in both feet while using the device. Figure 3 cross-analyses the subjective UPDRS scoring Q3.10 (gait) against the double support time. For every participant using the CUE[1], the measurements either improved or remained the same. For 2 of the 5 participants, the UPDRS and double support time both showed improvements. In Figure 4, the gait symmetry is plotted. 4 of the 5 participants already displayed near-perfect or perfect symmetry at baseline, rendering these results inconclusive. However, for the participant with more significant asymmetry, a noticeable improvement was observed.

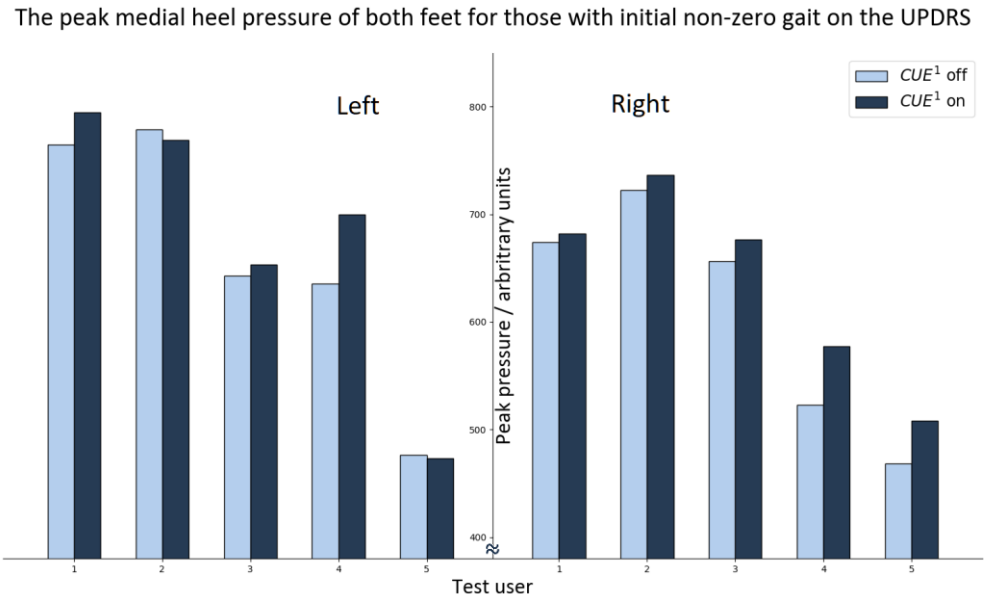


Figure 2: The peak medial heel pressure plotted for each foot and each participant with non-zero gait on the pre-device UPDRS assessment, with and without CUE[1].

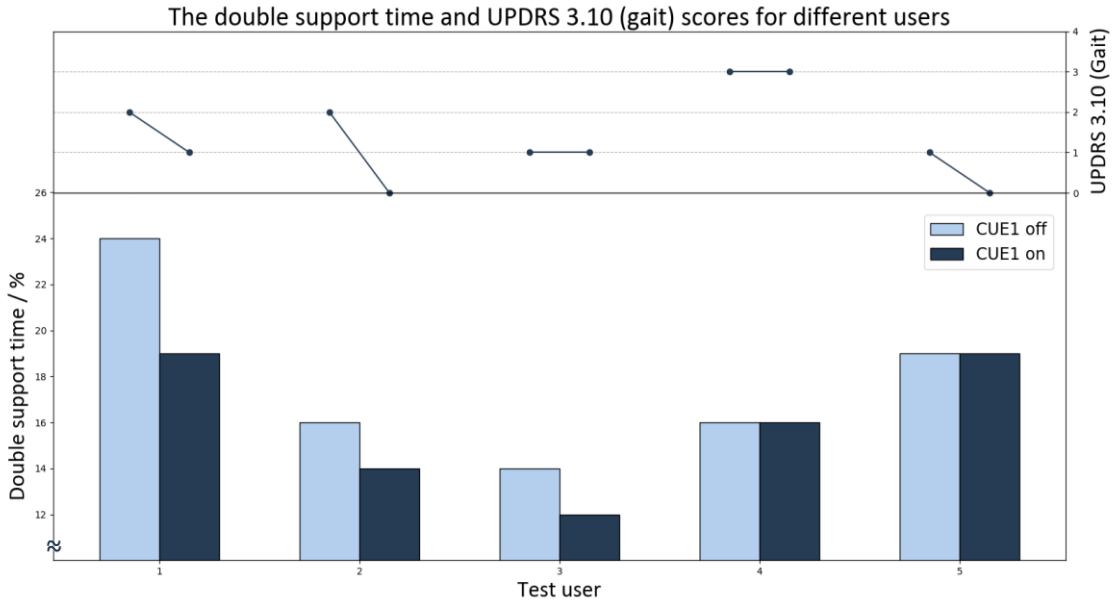


Figure 3: The double support time and UPDRS 3.10 scoring (gait) with and without CUE[1].

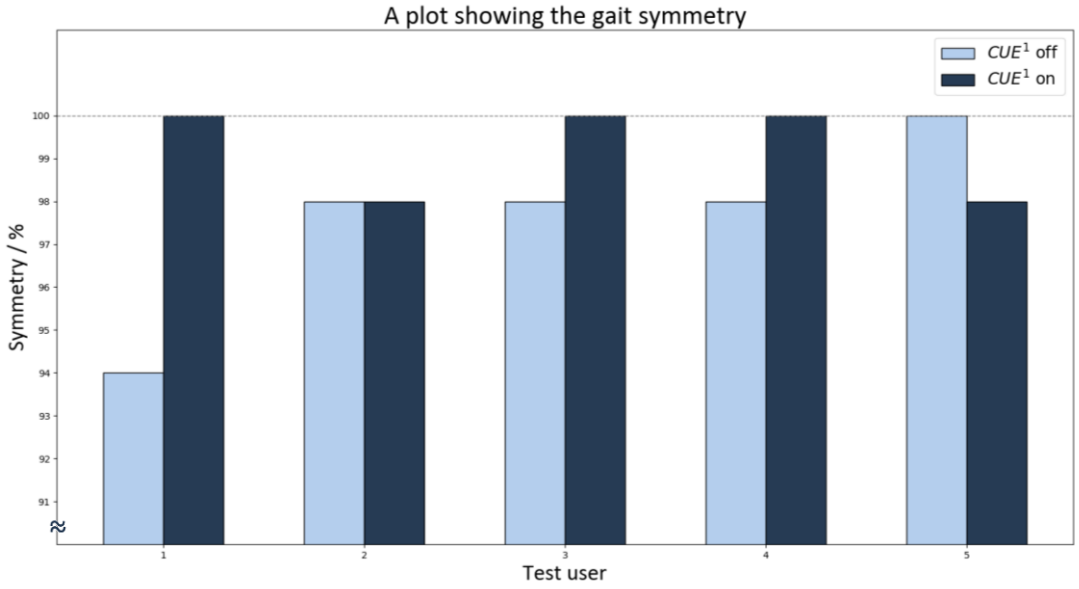


Figure 4: The gait symmetry as a percentage is plotted for each of the five participants, with and without CUE[1].

2.3 Discussion

Figure 2,3 and 4 provide promising support to the notion that the gait-related benefits of CUE[1] can be seen in objective measurements backed by literature. While Figure 2 does not show unanimous improvement in the medial peak heel pressure across both feet, it should be noted that gait-related symptoms of Parkinson's disease can often be one-sided. Non-improvements or small decreases in peak pressure would hence be expected in an asymptomatic leg due to random error.

Figure 3 shows promising improvement in double support time across three participants when using the CUE[1] device and no change across the other two. Two of the three participant's improvement were corroborated with an improvement in the UPDRS. This could indicate a potential lack of sensitivity in the UPDRS scoring. The

scale is only capable of rating gait symptom severity as an integer between 0 and 4 but the majority of PwP have ratings of between 0 and 2, leaving little room for quantifying improvements in symptoms.

Figure 4's data is inconclusive. While only participants with gait-related symptoms were picked for this study, the results from gait symmetry showed that 4 out of the 5 participants had near perfect or perfect gait symmetry. A difference of 49 to 50 is not significant and hence this analysis raises an issue with using gait symmetry as an objective gait-related symptom measurement. However, the single participant with significant asymmetry, Participant 1, did show marked improvement in symmetry when using the CUE[1] device. This suggests that while symmetry measurements are not particularly useful for a representative cohort of PwP, they could be useful for those with particularly asymmetrical gait.

While these measurements have been taken under the TuG 3m experimental condition, which is a standardised test used to assess Parkinsonian gait, free and longer-distance walking could be significantly more useful in the context of objective measurement.

3. Conclusion

In conclusion, the use of Stapp one's insole technology has been used to test the efficacy of CUE[1] in improving gait-related symptoms via objective metrics that in the literature have been shown to correlate with the severity of Parkinson's symptoms. **The findings were promising, with 100% of participants showing improvement across at least one of the metrics, and 60% showing improvement across two metrics (peak medial heel pressure and double support time).** The third metric, gait symmetry, had near perfect scores for 4 of the 5 participants and hence proved inconclusive across the cohort. However, for the one participant with asymmetrical gait, a marked improvement was seen. Further work needs to be done to assess if these results can be reproduced in a clinical setting, however these preliminary results provide promising evidence that CUE[1] is successful at improving gait-related symptoms in people with Parkinson's disease.

References

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