Clinical feasibility of a wearable, conformable sensor patch to monitor motor symptoms in Parkinson’s disease

Objective
- A two-part pilot study (PD0028) to evaluate the safety, tolerability and clinical feasibility of the prototype NIMBLE system sensor patch, as an objective and continuous measure of motor symptoms in patients with Parkinson’s disease (PD).

Background
- In current clinical practice, the assessment of motor symptoms in patients with PD involves assessment of patient historical data, patient diaries and neurological assessments and an examination by a physician.
- The Unified Parkinson’s Disease Rating Scale (UPDRS) is the most commonly used scale in the clinical assessment of PD, but it is subject to biased reporting of the examiner which can introduce errors and a lack of precision due to only short duration of motor neurological assessments performed in clinical practice.
- The NIMBLE patch consists of an accelerometer and an electromyography (EMG) sensor embedded into a flexible, conformable patch designed to measure and record symptom changes in movement and posture (Figure 1).

RESULTS

BASELINE DEMOGRAPHICS AND PARTICIPANT DISPOSITION (Table 1)
- In Part 1, 5 participants started and completed the study. 95.7% mean ± 7.0 standard deviation (SD) of total symptom assessments were performed over a 30-day period (average 10.3 days ± 4.4 standard deviation (SD) per participant).
- In Part 2, 21 participants (57.1% male; mean age 65.0 years ± 1.8 years) were included. 79.6% mean ± 10.2 standard deviation (SD) of total symptom assessments were performed over a 30-day period (average 11.1 days ± 4.0 standard deviation (SD) per participant).

ACCURACY OF PART 2 ALGORITHM FROM IN-CLINIC ASSESSMENTS (Table 2)
- The exact accuracy (error rate of 0) of predicted vs observed scores was 44.9% and the overall accuracy of predicting that score was 58.0%. Algorithms were more accurate for scores with more assessments. No 4s were observed for predicted scores.
- The correlation between predicted and observed motor PD assessment scores in relation to treatment was 0.73, which is significant (p=0.0002). The correlation between observed scores and NIMBLE patch output was 0.746, which is significant (p=0.0002).

ADHESIVENESS OF THE NIMBLE PATCH (Figure 2)
- Adhesiveness scores ranged from 0 (90% adhered [essentially no lift off the skin]) to 4 (0% adhered – device detached [patch completely off skin]).

OUTCOMES
- Participants were easily able to use the patch and it was not too painful to detach, and felt that it did not interfere with daily activities or sleep. They were very satisfied with the usage experience and not embarrassed to wear the patch in public. The patch did not interfere with daily activities or sleep. Participants found the patch easy to use, not too painful to detach, and felt that it did not interfere with daily activities or sleep. They were very satisfied with the usage experience and not embarrassed to wear the patch in public.

STATISTICAL ANALYSES
- Multiple algorithms were developed by MC10 to translate raw output from the patch into scores of motor symptom severity that could be analyzed to predicted scores.
- Motor symptoms were assessed independently by 2 examiners (ie participants were not observed by the same examiner).

ACKNOWLEDGEMENTS
- Michael Markowitz
- Email: ucbcares@ucb.com
- Phone: 844-599-CARE (2273)

IN-CLINIC MOTOR ASSESSMENT SCORES (Table 3)
- The average correlation coefficient between observed and predicted scores in Part 1 was 0.74, test–retest reliability and taping-up protocol had the highest correlations (Figure 3).

PARTICIPANT FEEDBACK (Table 4)
- Participants found the patch easy to use, not too painful to detach, and felt that it did not interfere with daily activities or sleep. They were very satisfied with the usage experience and not embarrassed to wear the patch in public. In addition, several participants found the information gathered from the patch to be valuable and trusted the DAP to be a useful tool and easy to use.

CONCLUSIONS
- The NIMBLE patch was safe and well tolerated.
- The correlation between predicted and observed motor PD symptom severity was a valuable tool expected to improve clinical algorithm refinement after further studies in larger groups of participants with a greater range of symptom severity.

Acknowledgements
- Michael Markowitz
- Email: ucbcares@ucb.com
- Phone: 844-599-CARE (2273)