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Point of view

Point of view: Wearable systems for at-home monitoring of motor complications in Parkinson's disease should deliver clinically actionable information

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1. Introduction

Parkinson's disease (PD) affects over six million people globally. PD leads to devastating chronic motor manifestations such as bradykinesia/akinesia, rigidity, gait disturbance, and tremor. PD symptoms are managed by adjusting the schedule and dose of PD medications such as levodopa and dopamine agonists. However, PD patients at mid- and advanced-stages of the disease frequently experience additional treatment-related motor complications such as troubling motor fluctuations between mobile (ON) and akinetic (OFF) states and abnormal, involuntary dyskinetic movements [1]. At this stage, effective medication adjustments require accurate knowledge about the nature of patients' motor complications over a typical day. The current clinical protocol entails obtaining this information through periodic clinical examinations and patient interviews. However, patient interviews can be unreliable and limited by recall bias [2]. Clinical examinations may only provide a snapshot of motor functioning, hence failing to capture an accurate picture of motor complications [3].

Rapid advancements in sensing technologies provide user-friendly wearables with a long battery life that can be worn by PD patients and used to unobtrusively assess motor symptoms during activities of daily living (ADL). Such sensing technologies can be tailored for use in monitoring PD patients at home to generate clinically actionable information that can be provided to the treating physician to make individualized therapeutic recommendations (Table 1) [4,5]. Commercially available wearable devices such as Kinesia360™ (Great Lakes NeuroTechnologies), Personal KinetiGraph® (PKG®) (Global Kinetics Corporation Ltd.), REMPARK (Sense4Care), and PERFORM [6] have various characteristics and deliverables to assess motor complications, but adoption and implementation in clinical practice have been slow and limited [7]. Contributing factors to such inconsistency might include delays in patient acceptance and adherence to wearing new technology, clinician acceptance, or issues with cost and insurance coverage. However, in an attempt to look beyond the technology life cycle to better understand this inconsistency, we sought to review the current status of these devices and explore possible gaps between the capabilities of their underlying algorithms compared to the requirements for an accurate motor complication monitoring system that can facilitate effective therapeutic adjustments. It is our view that a major factor contributing to slow adoption of at-home monitoring systems of motor complications is based on the practical utility of the existing deliverables from such devices, which are mainly determined by their underlying algorithms. We propose that if revised algorithms can be used to generate data that can be interpreted more reliably in the context of widely accepted and understood clinical measures, this would create more convincing evidence for the clinicians to utilize these devices and the insurance companies to support coverage.

1.1. Requirements of a motor complication monitoring system

For a monitoring device to be effectively used to inform therapy adjustments, it needs to provide a comprehensive picture of motor

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Table 1
Clinically actionable information required for precise identification of therapeutic goals and example medication adjustments to optimize PD control.

Clinically Actionable Information	Therapeutic Goals	Examples of Medication Adjustments
Duration of OFF state **Duration of ON state**	**Reduce OFF time** (longer time spent in ON time with each dose)	Add COMT-I, MAO-I, new dopaminergic medication, increase dose of existing dopaminergic medication, reducing interval of dopaminergic medication dosing
Change in MDS-UPDRS-III severity between OFF and ON states **Change in tremor severity from OFF and ON states**	**Improve quality of ON time** (greater degree of symptom improvement with each dose)	Increase dose of dopaminergic medication, add a new dopaminergic medication, add trihexyphenidyl (for tremor only)
Duration of OND state **Change in dyskinesia severity from OFF and ON states**	**Reduce dyskinesia severity or duration**	Add amantadine or lower dose of dopaminergic medication

complications using objective measures comparable to the clinically actionable information (Table 1) obtained from routine assessment tools (e.g., interview and examination). The average time spent in ON, OFF, and OND (ON with peak dose or diphasic dyskinesia) states and the degree of change in symptom severity over a typical day are important considerations. Three measurements of PD symptoms relevant for medication adjustments are: 1) Movement Disorder Society Unified PD Rating Scale (MDS-UPDRS) Part-III to measure motor symptoms in each state; 2) tremor severity as the physician may decide to pursue specific medications for tremor management only; 3) the Unified Dyskinesia Rating Score or Modified Abnormal Involuntary Movement Scale (mAIMS) to understand dyskinesia severity.

1.2. Introduction to commercially available systems

Kinesia360™ uses sensors on the most affected wrist and ankle to estimate the severity (scale of 0–4 for severe) of tremor, bradykinesia, and dyskinesia, and a patient diary application to collect information about medication states. PKG® uses one sensor on the wrist and provides a bradykinesia score (BKS) and dyskinesia score (DKS) ranging from 0 to 4 (severe), the occurrence of tremor, and a fluctuation and dyskinesia score (FDS), derived from BKS and DKS scores for describing motor fluctuations [8,9]. BKS, DKS, and FDS are new measures that are not presently obtainable during interviews or examinations. Sense4-Care/REMPARK uses sensors on the wrist and waist to portray intervals with tremor, bradykinesia, dyskinesia, medication ON/OFF states, and freezing of gait and fall incidents without severity scores [10]. Other devices either require multiple wearables (three in SENSE-PARK [11] or five in PERFORM [6]) or include peripheral tools, such as a balance board and touch screen computer to perform prescribed tests, which pose challenges for large-scale deployment. Other systems, such as mPower [12] and Medopad (https://medopad.com), require patients' active engagement (e.g., tapping or performing UPDRS-specific tasks in front of a smartphone camera) and therefore, cannot achieve unobtrusive, continuous monitoring. Such devices are unable to detect durations of medication states and the transition periods (e.g., ON to OFF or ON to OND) that are important factors for medication adjustment and may be more suitable for early PD detection rather than the measurement of motor complications.

2. Ideal device capabilities for at-home monitoring of motor complications

2.1. Measurement and reporting of clinically actionable information

The systems described above measure and provide only some elements of the clinically actionable information in Table 1. Kinesia360™ does not passively measure or report time spent in different medication states and instead asks patients' active engagement to report this information using the diary application. Although the report provides a measure of symptom duration and severity, it does not readily match this to ON, OFF, and OND states. Tremor severity is not provided in the PKG® report. The system only reports a new measure of dyskinesia and bradykinesia severity with respect to the median, and 25th and 75th percentile of a healthy control group averaged over multiple days. Farzanehfar et al. [13] show that it may still take 2–4 clinical visits to translate these indices into clinically meaningful metrics by performing additional examinations and patient interviews. The Sense4Care report only detects the duration of different states and does not provide any information on the severity of the tremor, bradykinesia, or dyskinesia. Table 2 lists each devices' deliverables along with the characteristics of their underlying algorithms.

We propose that developing and implementing refined algorithms that measure the full spectrum of clinically actionable information will facilitate clinicians' confidence that these devices can inform disease management and will enhance patient-clinician communication about disease manifestations.

2.2. Agreement with clinically accepted measures

The reports provided by such systems are only as accurate as their underlying algorithms, which are challenged by the difficulty of estimating motor complications from ADL during free-living conditions. For example, Pulliam et al. [22] show that the Kinesia360™ algorithms provide good detection accuracy in a simulated home setting study of 13 PD patients, while showing a low estimation of dyskinesia ($r = 0.45$) and tremor ($r = 0.58$) when used on 12 PD patients at home as shown by Hadley et al. [23].

Griffiths et al. [18] show that PKG® algorithms derive a high correlation for DKS ($r = 0.8$) and BKS ($r = 0.63$) in the simulated home environment. However, in an actual home setting, Horne et al. [19] show that the DKS correlation was only 0.49 after excluding the patients without dyskinesia ($n = 46$), even though PKG® detected substantial dyskinesia in 11% ($n = 5$) of those patients. Furthermore, in the home setting, the BKS correlation during ON state was $r = 0.42$. PKG®-measured distributions of hours per day spent in different motor states showed 0.404–0.658 correlation to diary categorizations, and a 0.215–0.324 correlation was found when motor states were assessed at the single-hour-level [24]. In a study with 12 patients with ($n = 5$) and without ($n = 7$) fluctuations, Horne et al., 2015 [25] show a 97.1% sensitivity and 87.5% specificity for detecting motor fluctuations. However, the algorithmically-derived FDS score has not been correlated with the clinically-measured severity of fluctuation and requires additional clinician interpretation. Khodakarami et al., 2019 [20] develop a new algorithm (not included PKG®) to detect clinically meaningful percent change in UPDRS III from OFF to ON states (i.e., absΔUPDRS III$>$10), achieving 74% accuracy before removing 83 participants for different reasons such as not being in their worst OFF state, uncertainty in the UPDRS III change (removing patients with 11$\leq$absΔUPDRS III$\leq$14), or variability in the magnitude and latency of peak response to levodopa.

Using parameters measured by Sense4Care, Rodríguez-Molinero et al., 2017 [21] obtain a −0.56 correlation with the total UPDRS-III, and Samà et al., 2017 [14] obtain a correlation of −0.81 with the bradykinesia item 24 of the UPDRS III. Bayés et al. [15] investigate the ability of Sense4Care measurements to detect ON and OFF states in 33

Table 2
Characteristics of three commercially available devices and a recommended monitoring system for assessment of motor complications in PD patients at home. BKS, DKS, and FDS stand for bradykinesia score, dyskinesia score, and fluctuation and dyskinesia score, respectively.

		Kinesia 360™	PKG®	Sense4Care	Recommended System
Number of sensors: locations		2: Most affected wrist and ankle	1: Most affected wrist	2: Waist and most affected wrist	2: Most affected wrist and ankle
Clinically actionable data	**Medication ON/OFF/OND duration**	× Not automated. × Patients enter medication states using a diary app.	× Every hour detections are averaged over at least five-day use.	× Every hour detections during a limited range of ADL [14].	✓ Every half-hour detection according to the patient's baseline during ADL.
	Severity ratings	× Does not readily match to ON/OFF/OND states.	× Missing tremor severity [15]. × Creates new measures of symptom severity (i.e., BKS, DKS, FDS).	× Only measures duration of symptoms; missing severity ratings. × Only limited ADL [16].	✓ Make clinically meaningful measurements of tremor, dyskinesia, MDS-UPDRS III during ADL.
Algorithm Characteristics	**Accuracy during ADL**	× Low correlation with UPDRS measurements when used in home settings [17].	× Low correlation with at-home [18,19] compared to in-clinic monitoring. × One wrist sensor does not capture disease manifestations on the lower limb.	× Low correlation with UPDRS III [20]. × Tremor algorithm uses only wrist sensor data and bradykinesia/ dyskinesia only the waist sensor data.	✓ Provide high agreement when compared to clinically meaningful metrics. ✓ Simultaneous analysis of sensors' data to capture disease manifestations on both the lower and upper limb.
	Continuous/ Unobtrusive	× No, requires patients reporting medication states.	× Measurements are averaged over at least five-day use to reduce error [18,19], thereby missing day-to-day variations.	× Not a continuous estimation during all ADL [21,16]. × Transition periods between OFF and ON are excluded from analysis [14].	✓ Continuous and automated measurements during all ADL.
	Interpretability to an individual patient	× Symptom severity measures do not readily match to ON, OFF, and OND states and further clinical correlation is required.	× Medication state detection is not individualized to each patient's own baseline. × Severity ratings are based on comparison to healthy controls.	× Medication state detection is not individualized to each patient's own baseline. × Missing severity ratings.	✓ Detect medication states customized to a patient's baseline. ✓ Estimate clinically interpretable severity measures to identify intra-individual changes of severity.

PD patients during three days of home monitoring. Accuracy for ON detection was 88% and 97% for OFF detection, but only used an average of five predictions per patient over three days after performing extreme post-processing of the results, such as excluding patient-reported medication states that differed over two consecutive hours [15]. It is, therefore, unclear how the system performs during transition periods between OFF and ON.

In summary, existing algorithms provide only some clinically actionable information, and they also perform differently between controlled and home settings. Significant data exclusions or other post-processing techniques are required to show acceptable agreement with clinically recognized measures of symptom severity or ON/OFF states, and the reduced performance in the home setting has not yet been explored. The use of algorithms that can better relate passive measurements to clinical measurements combined with the use of data characteristics to investigate or explain mismatches would further enhance clinician confidence in the utility and value of these devices.

2.3. Reporting the full spectrum of disease variability

Available systems do not fully report the variability in motor features that may occur in a patient's living environment and do not report all aspects of disease severity. For example, Kinesia360™ does not provide medication states. PKG® only detects the presence or absence of hand tremor as explained by Braybrook et al. [17], and tremor fluctuations are not incorporated into the FDS score. A change in the dyskinesia mainly drives the PKG® FDS score, and Ossig et al. [24] show that the method is not sensitive to change in BKS before and after DBS. Additionally, using only one wrist sensor, PKG® does not capture PD manifestations in the lower extremities. As explained in the related references, Sense4Care only detects intervals with hand tremor [16]. Although Sense4Care uses two sensors, the data from each sensor is not integrated. For example, the wrist sensor only employs a tremor algorithm [16], while the waist sensor is used separately to measure lower limb dyskinetic movements [26] and bradykinesia [14].

PKG® has to be worn at least five days and only reports an average report of its metrics across those days per patient to reduce the error in BKS and DKS estimations [19] and motor states [24]. Day-to-day variations are, therefore, less apparent. Sense4Care does not identify variability because it does not detect PD motor features during all ADL. For example, it does not detect dyskinesia during ambulation as shown by Samà et al. [14], and bradykinesia is only assessed during ambulation as shown in the work of Pérez-López et al. [26]. The OFF state is detected in ambulatory conditions by the presence of gait bradykinesia, and the ON state is detected as the absence of bradykinesia during walking, or dyskinesia when not walking.

It is well understood that PD manifestations vary substantially between individuals and that different motor phenotypes exist (i.e., tremor-dominant and postural instability gait disturbance subtypes of PD). Algorithms in unobtrusive monitoring systems should use features that identify fluctuating and dyskinetic or undertreated patients based on clinically actionable information regardless of an individual's specific manifestations, active therapy, or activity level.

2.4. Interpretability of the report for an individual patient and implications for clinical practice

The devices reviewed in this paper provide new objective measures referenced to group "norms" derived from either a group of PD patients or healthy controls. When estimating PD severity ratings, a change in the new measures provides a sense of severity relative to the group level, but what this degree of change means to the patient's disease state and how the clinician can use that information to adjust medication is unknown unless those metrics represent a clinically meaningful metric relevant to that patient. As a result, the reports from these devices can capture inter-individual variations relative to the group level but are generally unable

to identify intra-individual changes relevant to the patient's baseline [7].

In the case of medication state detection, where one patient's OFF state severity could be similar to another patient's ON state (see Fig. 1 from our PD patient data [27]), comparison to other PD patients or healthy controls may miss intra-individual variations in disease manifestations and inaccurately characterize the individual as ON or OFF at all time-points. Unless there are algorithms that can detect medication states relative to the patient's baseline, the device cannot provide accurate measurements of medication state.

Additionally, the implications for clinical practice when using these devices are not robustly demonstrated in existing studies. In a recent study by Isaacson et al., 2019 [28], Kinesia360™ data did not reflect improvements in PD symptoms after treatment with rotigotine, though UPDRS III did. Horne et al., 2016 [19] explored PKG® to demonstrate motor improvements following DBS. Both the mAIMS and DKS scores reflected a reduction in dyskinesia with DBS. However, BKS could not show the effect of DBS, although there was a difference in clinician-measured UDPRS III scores before and after DBS. Joshi et al., 2019 [29] found that across 85 visits in 63 patients, PKG® use improved the ability to assess the impact of therapy in 38% of visits and improved dialogue with patients in 59% of the visits. PKG® identified symptoms that were not reported by 48% of the patients while missing a symptom in 24%. In another study [30], 59% of PKG® reports (n = 112) did not provide additional information beyond routine clinical evaluation, and its use resulted in adjusting the patient's medical management in 32% of cases. A study by Farzanehfar et al., 2018 [31] showed amongst 33 PD patients, 14 required therapeutic adjustments and a median of 3 additional clinical visits (range 2–4) were required following PKG® reporting to achieve therapeutic goals) for 14 (out of 33) PD patients.

For a device to be relevant to clinical decision-making or positively impact clinical practice, the algorithms within them should robustly consider both inter- and intra-individual comparisons and directly deliver the information about clinically actionable information in the device report.

3. Conclusions

Despite the significant potential of using commercially available wearable systems for unobtrusive assessment of PD motor complications during ADLs, their adoption and implementation have not been robust. Our investigation of these devices indicates that their onboard, interpretive algorithms do not necessarily provide complete information and may not be tailored for individualized patient care. One may suggest that the existing discrepancy between these devices and the clinical gold-standard assessments might indicate their ability to provide additional information beyond the clinical assessments. If that is the case, more research is needed to apply the knowledge learned to the disease state; otherwise the existing gap in adopting and implementing such devices will remain. Specifically, for measuring motor symptoms that inform disease management and for clinicians to feel comfortable with their use, these devices need to generate data that can be interpreted alongside widely accepted and understood clinical measures. A better definition of accuracy of these outcomes with respect to the clinical gold-standard assessments is needed to address the issues with the subjectivity of these gold-standard measures. Moreover, when there is a disagreement between these technology measures and the gold-standard, more analysis is needed to interpret the differences, which could lead to additional information gained by technology.

We propose that obstacles to adoption relate largely to the limitations of these devices' underlying algorithms, which currently generate data that is not individualized and not sensitive to change at the patient level. Furthermore, current algorithms do not provide all the required information about motor complications, are based on comparative metrics, or do not provide a full spectrum of the disease severity during ADLs in the home environment. Consequently, these systems have

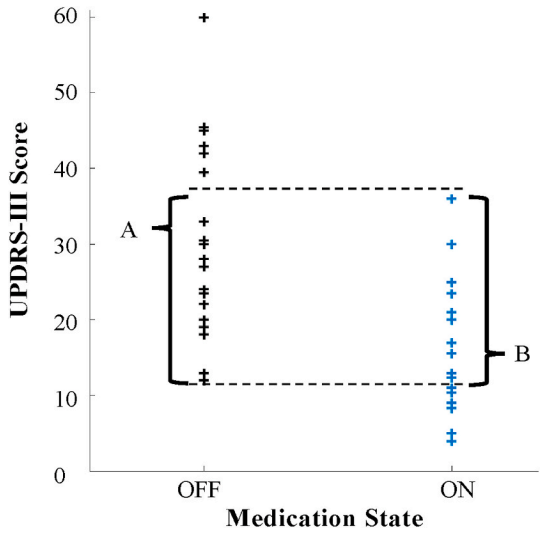

Fig. 1. MDS-UPDRS-III scores of 19 PD subjects in OFF and ON states [28]. Although in different states, subjects in groups A and B have similar MDS-UPDRS-III scores indicating that medication state has to be detected individually and not from disease severity.

limited capability to accurately and comprehensively report clinically actionable information and still require either additional patient participation or clinical assessment to inform therapeutic decision-making. The essential characteristics and deliverables of a system that can address these limitations are listed in Table 2. Such systems with readily interpretable data will enhance patient-clinician communication about disease manifestations. They can facilitate understanding of the association between various symptoms and the clinical state, or the interpretation of the digital parameters.

Additional individualization of technology-based assessments such as the number and placement of the sensors according to the patient's need and a capability to monitor the patient's adherence to the device use could further improve the applicability of these devices. However, with the recent advances in engineering and algorithm development, we recommend developing optimized algorithms that find the optimal inflection point between accuracy and complexity without adding more layers of complexity to encourage patients' enthusiasm and adoptability. Non-motor symptom detection via wearable sensors poses separate and unique challenges, and is unlikely to be accomplished using the same unobtrusive techniques as motor symptom detection. However, when separately assessed, they can be considered alongside the data generated from devices intended to measure motor complications to determine the relationship of these symptoms to ON or OFF status for clinicians to select the most appropriate medication plan. Lastly, there is growing interest in developing technology to meet patient-centered needs [32], and the development of new algorithms could accomplish this by prioritizing novel digital endpoints (https://aact.ctti-clinicaltrials.org/).

We acknowledge that there may be other factors which are beyond the scope of this paper which may impact the adoptability of wearable systems to monitor motor complications. Regardless, we believe that an unobtrusive home monitoring system for measurement of motor complications that is equipped with new or refined algorithms meeting key requirements as described in this viewpoint will be better positioned for clinical adoption by a wide variety of care providers involved in managing PD patients.

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