Identifying Functional Phenotypes of Chronic Low Back Pain using Wearable Sensor Enabled Functional Assessments

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INTRODUCTION: Chronic Low Back Pain (cLBP) stands as the leading cause of long-term disability. It ranks as the most common condition for which opioids are prescribed, potentially contributing to the opioid crisis. Despite the increased use of diverse interventions and imaging technologies, cLBP's prevalence persists, accompanied by escalating medical costs and no discernible improvement in outcomes. Even though evidence-based treatments exist, finding the best treatment for individual patients is a daunting and resource-intensive task. This challenge arises, in part, from the multifaceted nature of cLBP. It's not a simple, singular condition but rather a complex interplay of physical, mental, and social factors that influence its onset, progression, evolution, and resolution. Moreover, the lack of objective metrics to help reliably characterize a patient's condition further complicates clinical decision-making, leading to generalized treatment strategies for a diverse population rather than tailored approaches for individual patient phenotypes. Consequently, the incorporation of objective metrics along with the identification of meaningful clinical phenotypes has the potential to enhance clinical decision-making, refine treatment strategies, and ultimately improve patient outcomes in spine care. To address this problem, the aim of our study was to identify clinical phenotypes of cLBP using machine learning and data captured from novel wearable sensor-enabled functional motion assessments, examine their association with relevant biopsychosocial factors of spine health and prospectively assess their treatment response trajectories over time.

METHODS: This study was a prospective observational study involving 509 patients with cLBP who underwent standard-of-care interventions. Participants filled out questionnaires covering key biopsychosocial domains (pain intensity, pain interference, physical function, anxiety, depression, etc.) and underwent a 10-minute functional spine motion assessment using a wearable motion sensing system (see Figure 1). The functional motion assessment aimed to capture the 3-dimensional kinematic performance of the spine as participants executed a set of standardized dynamic trunk motion tests under controlled conditions. During the assessment, participants performed dynamic trunk motions in three anatomical planes: flexing and extending for sagittal movements, bending right to left for lateral movements, and twisting right to left for axial movements. The collected data were automatically processed to extract motion features (positions, peak velocities, and accelerations), which were then normalized to a reference population of healthy controls. This normalization allows for benchmarking of functional state and provides context on functional severity. The resulting functional or probability of normal score (pN) ranges from 0 to 100, with higher scores indicating healthier function relative to the individual's age and sex. Both the questionnaires and functional motion assessments were conducted at baseline and at 3-month follow-up to facilitate the discovery of phenotypes, assess disease progression, and document cluster trajectories relative to treatments. Approval for the study was granted by The Ohio State University's Institutional Review Board, and participants provided informed consent before enrollment. The primary analysis utilized unsupervised clustering analysis to identify phenotypes based on baseline functional scores. Descriptive statistics and paired t-tests were applied to characterize individual clusters, examine cluster differences across biopsychosocial variables, and explore longitudinal trajectories. Statistical significance was set at p-values < 0.05.

RESULTS SECTION: Our cLBP patient cohort comprised of 173 males and 366 females with a mean age of 50.3 ± 14.5 years. Using unsupervised clustering analysis, we identified 4 distinct functional clusters that indicated varying degrees of functional severity relative to age and sex matched healthy controls as well as varying pain severity (see Figure 2). Cluster 1 (High function) comprised of 102 patients with notably high functional scores ($pN = 77 \pm 9$) and low pain intensity; Cluster 2 (Moderate function) comprised of 166 patients with moderately scored functional profiles ($pN=51 \pm 14$); Cluster 3 (Poor function) involved 169 patients exhibiting functional scores ($pN =37 \pm 17$) indicative of suboptimal kinematics; and Cluster 4 (Very poor function) comprised 118 patients with high pain intensity and low functional scores ($pN = 10 \pm 4$) that were significantly below those of healthy controls. Our findings also revealed a noteworthy increase in pain severity across the identified clusters. In examining longitudinal responses at the 3-month follow-up, we observed that 65% of patients in Cluster 1 (High function) and 62% in Cluster 2 (Moderate function) exhibited meaningful improvements in pain, whereas 47% in Cluster 3 (Poor function) and only 38% in Cluster 4 (Very poor function) reported pain relief. Notably, when exploring the transition between clusters at 3 months (see Figure 3), a substantial proportion of patients from Clusters 1 to 3 shifted to Cluster 4 (Very poor function). These results underscore the variability in recovery trajectories among patients within these functional clusters.

DISCUSSION: Our study found 4 distinct clinical phenotypes with varying degrees of pain and functional severity. We also showed that the recovery profiles for these clusters were different and patients transitioned between these clusters at follow-up after treatment. This information indicates that: (a) clustering using motion features from wearable sensors is feasible; (b) may assist in objectively differentiating functional severity; and (c) inform clinical decision making on optimizing care for patients within specific phenotypes that are at risk of transitioning to more severe clusters.

SIGNIFICANCE/CLINICAL RELEVANCE: This study suggests that wearable sensor enabled functional assessments can identify clinical phenotypes and may lead to a better understanding of how cLBP impacts different patient subgroups. This information has the potential to benefit clinical trial designs, enhance clinical decision-making on assessing functional severity and optimizing treatment strategies for cLBP phenotypes in order to maximize clinical benefits and minimize medical costs.

REFERENCES: Hoy et al. Ann Rheum Dis (2015); Dieleman et al. J Am Med Assoc. (2016); Kerbs et al JAMA (2018); Marras et al. Spine (1999)

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IMAGES AND TABLES:

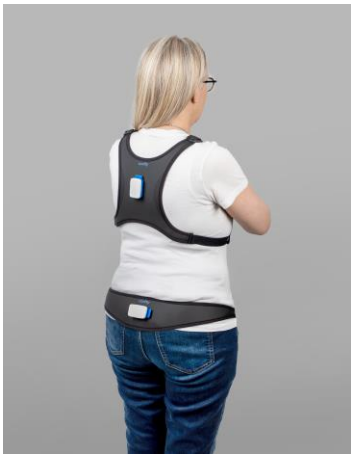

Figure 1: Wearable Motion System showing back and pelvic harnesses and sensor configuration for use in functional evaluations

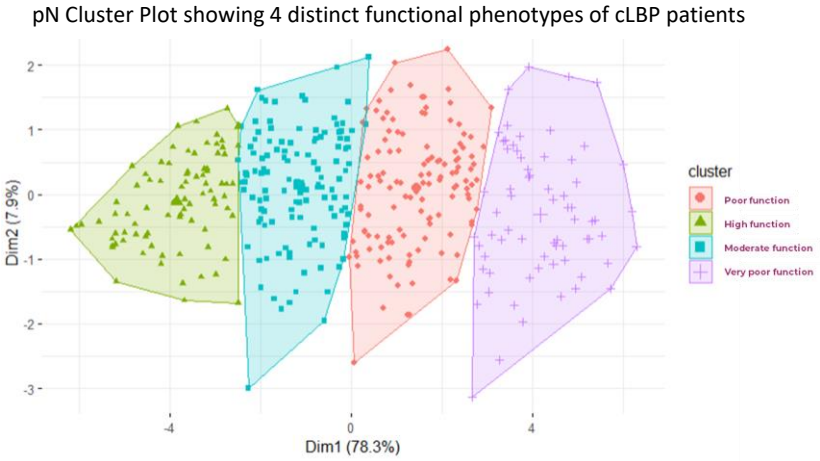

Figure 2: 4 distinct clusters (High function, Moderate function, Poor function and Very poor function) generated using motion features showed variations in functional severity with cLBP. High function cluster comprised of patients with comparable functional movements to healthy controls while on the other end, the Very poor function cluster indicated significantly diminished functional movements.

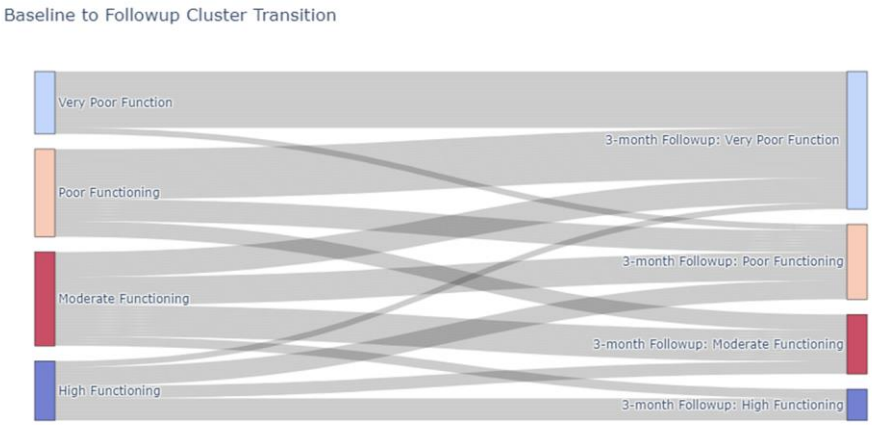

Figure 3: Highlights the transition of patients from their baseline clusters to other clusters at 3 month follow-up. In our study, we found a significant proportion of patients transitioned to over to the Very poor function cluster at follow-up indicating failed treatments and increasing need to optimize specific treatments for high risk phenotypes..