Wearable motion-based platform for functional spine health assessment

Prasath Mageswaran,1 Jonathan Dufour,1 Alexander Aurand,1 Gregory Knapik,1 Hamed Hani,1 Dukagjin M Blakaj,1,2 Safdar Khan,1,3 Nasir Hussain,1 Maneesh Tiwari,1 Jayesh Vallabh,1,4 Tristan Weaver,1,5 William S Marras1

ABSTRACT

Introduction Low back pain is a significant burden to society and the lack of reliable outcome measures, combined with a prevailing inability to quantify the biopsychosocial elements implicated in the disease, impedes clinical decision-making and distorts treatment efficacy. This paper aims to validate the utility of a biopsychosocial spine platform to provide standardized wearable sensor-derived functional motion assessments to assess spine function and differentiate between healthy controls and patients. Secondly, we explored the correlation between these motion features and subjective biopsychosocial measures.

Methods An observational study was conducted on healthy controls (n=50) and patients with low back pain (n=50) to validate platform utility. The platform was used to conduct functional assessments along with patient-reported outcome assessments to holistically document cohort differences. Our primary outcomes were motion features; and our secondary outcomes were biopsychosocial measures (pain, function, etc).

Results Our results demonstrated statistically significant differences in motion features between healthy and patient cohorts across anatomical planes. Importantly, we found velocity and acceleration in the axial plane showed the largest difference, with healthy controls having 49.7% and 55.7% higher values, respectively, than patients. In addition, we found significant correlations between motion features and biopsychosocial measures.

Conclusions Our study validated the use of wearable sensor-derived functional motion metrics in differentiating healthy controls and patients. Collectively, this technology has the potential to facilitate holistic biopsychosocial evaluations to enhance spine care and improve patient outcomes.

Trial registration number NCT05776771.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Low back disorders are a significant burden to society and the lack of reliable measures, combined with a prevailing inability to quantify the biopsychosocial elements implicated in the disease, impedes clinical decision-making and distorts treatment efficacy.

WHAT THIS STUDY ADDS

⇒ This research highlights the innovative use of a spine health platform that leverages modern wearable motion sensors and cloud-based computing to provide rapid access to reliable functional motion metrics to support clinical decision-making in spine care.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The use of functional motion metrics has the potential to shift clinical paradigms and provide objective information to better assess treatment effect and disease trajectory over time.

INTRODUCTION

Low back disorders (LBDs) that lead to low back pain (LBP) continue to be one of the most prevalent and complex musculoskeletal disorders facing society.1–7 They represent the most disabling condition in the world8 and afflict up to 80% of the population at some point during one’s lifetime.9–11 Current treatment strategies are often ineffective and produce poor outcomes, increased addiction to opioids,12–15 unnecessary patient suffering, and inflated medical costs of over US$134 billion.16–17

Meaningful outcome measures for LBD have proven difficult to develop due to the complex interplay between physical, psychological, and social elements. The lack of reliable measures, combined with a prevailing inability to quantify the biopsychosocial elements implicated in the disease, impedes clinical decision-making and distorts treatment efficacy. This absence of objective metrics has often propagated a trial-and-error approach to treatment, culminating in escalating costs and suboptimal patient outcomes in spine care. Consequently, the development and validation of objective metrics could be instrumental in improving treatment strategies and outcomes.

While it remains a challenge to quantify many of the biopsychosocial elements that influence LBDs, an often underexplored component that has the capacity to serve as an indirect measure of biomechanical function is spine kinematics. Access to spine kinematics may offer an objective means to measure disease burden and assess treatment response. Indirect measurements of biomechanical or physiological function are commonly used as objective metrics in other chronic health conditions such as heart disease (heart rate, blood pressure) and diabetes (A1C), yet none exist for LBDs. There is evidence to suggest that spine kinematics can
provide a ‘window’ into the biomechanical functioning of the spine and has the potential to provide objective information to better assess treatment effect and disease trajectory over time. Previous research has shown that kinematic profiles of LBD sufferers are different from asymptomatic counterparts and these differences can be leveraged to inform clinical decision-making and treatment evaluation.

Over multiple decades, our team has helped lay the groundwork for leveraging spine kinematics as quantitative metrics for spine health outcome assessment. These efforts led to the development of the first wearable spine motion sensing system called the clinical lumbar motion monitor (cLMM), which uses measures of three-dimensional (3D) spine motion obtained via a functional spine assessment to provide biomechanically meaningful metrics of spine health. This functional motion test provides a rapid, non-invasive, cost-effective solution to objectively benchmark a patient’s spine function, and monitor functional improvement or decline with treatment over time. Since then, with emerging technologies in cloud-computing and inertial measurement unit (IMU) systems, the cLMM has evolved into a comprehensive spine health platform (Conity) designed to collect data at scale, integrating functional motion from IMU sensors to provide centralized access to functional metrics and a holistic array of biopsychosocial metrics to facilitate deep phenotyping of patients and enhance clinical decision-making for spine care.

This paper’s primary aim was to validate the utility of a biopsychosocial spine platform to provide standardized wearable sensor-derived functional motion features to assess spine function and identify kinematic differences between healthy controls and patients with LBP. Our secondary aim was to investigate the correlation between these functional motion features and subjective measures that target pain, function and other critical biopsychosocial domains.

METHODS
Study design and population
This is a single-center, observational study that compared the functional motion profiles of participants seeking medical care for chronic LBP (n=50) to healthy controls (n=50). A wearable spine health platform (Conity) was used to administer a 10 min standardized functional motion assessment of the lumbarthoracic (trunk) spine to document motion performance differences between the two cohorts. All participants (healthy controls and patients with LBP) were recruited based on eligibility criteria and medical history. Prior to participant enrolment, a research team member explained the study in detail, confirmed eligibility per study protocol, and obtained informed consent. The clinical trial registration details are as follows:

Name: The Spine Phenome Project.
Registration Date: February 6, 2023.
Clinical Trials Registration #: NCT05776771.

Healthy controls
Our healthy control participants were adults without known history of LBDs from Columbus and surrounding communities in Ohio. The inclusion criteria were: (a) age of 18 years or older; (b) able to stand for 10 min; (c) able to speak, read and understand English. The exclusion criteria were: (a) currently seeing or planning to see a medical provider for LBP; (b) history of chronic LBP lasting longer than 3 months; (c) neoplasia including history of brain or spine cancer; (d) spinal deformity requiring medical treatment; (e) history of spinal fractures; (f) known pregnancy; (g) spinal infection; (h) current condition requiring immobilization or bracing of the spine; (i) history of spine surgery; (j) known osteoporosis; (k) current open wounds in the back; and (l) any reason that a researcher or participant determines it is unsafe to participate in the study.

LBP patient sample
Our patient participants were adults with LBD that sought a medical consult at the Ohio State University Wexner Medical Center (OSUWMC). The inclusion criteria were: (a) age of 18 years or older; (b) history of chronic medical consult with primary complaint of LBP; (c) able to stand for 10 min; and (d) able to speak, read and understand English. The exclusion criteria were: (a) known pregnancy; (b) current LBP is the result of a traumatic injury or is positive for spine instability with imaging; (c) neoplasia including history of brain or spine cancer; (d) spinal deformity requiring medical treatment, (e) known spinal fractures in the last 6 months; (f) spinal infection; (g) current condition requiring immobilization or bracing of the spine; (h) spinal fusion across four or more lumbar disc levels; (i) known osteoporosis; (j) current open wounds in the back; (k) known unstable spondylolisthesis; and (l) any reason that a treating physician, researcher or participant determines it is unsafe to participate in the study.

Study procedure
Enrolled participants completed a series of Patient-Reported Outcome (PRO) questionnaires that spanned across critical biopsychosocial domains, prior to performing a 10 min functional motion assessment administered using a spine health platform (Conity). Details on the spine health platform are presented in online supplemental section. All data were collected in the Conity platform, which is depicted in figure 1.

A general overview of the functional assessment is presented below:

Functional spine motion assessment (Conity test)
The concept behind the functional spine motion assessment is to have participants perform a standardized dynamic motion test in a controlled manner to document the 3D kinematic performance capabilities of the spine. The standardized test is designed to take approximately 10 min from start to finish. Participants perform these dynamic trunk motions in each of three anatomical planes (flexing and extending back to neutral posture for sagittal movements, bending right to left for lateral movements, and twisting right to left for axial movements). Our instructors ask participants to perform the motions as fast or as far as they can comfortably. All motions are recorded directly into the Conity platform. Custom IMU motion sensors are mounted on harnesses (figure 2) worn on the chest and pelvis (for testing spine function). The harnesses are worn over clothing and take approximately 30 s to don and doff. One advantage of this hardware setup is that there is no need for the participant to disrobe. Another advantage is that there is no risk of adverse reactions from adhesives applied to the skin. The system has been designed to accommodate a broad range of participant body types ranging between the 1st and 99th percentile in height and weight.

The platform software was designed to enhance standardized testing among both participants and evaluators. The software contains embedded audio, video, and graphic instructions for participants and evaluators to walk them through the data collection protocol (figure 3). It also contains a standardized
online training program to teach new evaluators how to perform the evaluation and will prevent users from collecting data if they have not completed their training. Furthermore, collected data are automatically processed, analyzed, and available for reporting immediately after collection. Standardized questionnaires are scored, and motion assessment data are summarized for intuitive interpretation of motion performance results. The relevant kinematic components of interest extracted from the functional assessment and presented in this study consist of rotational position, maximum velocity, and acceleration measures across axial, lateral and sagittal anatomical planes. In general, these software features make the test easy to perform quickly, accurately, reliably, and safely.

Outcome measures
Primary outcomes: functional motion features
Our primary outcomes were functional motion features extracted from the lumbothoracic spine (trunk) and summarized as total range of motion (ROM), maximum velocity and acceleration ranges across the three anatomical planes (axial, lateral and sagittal).

Secondary outcomes: PROMIS physical, mental and social domains
In order to capture a holistic biopsychosocial picture of the variations between healthy controls and LBP patient participants, our secondary outcomes included: PROMIS item banks to assess average pain intensity (over 7 days) using a scale of 0 (no pain) to 10 (worst pain imaginable) as well as pain interference, physical function, depression, anxiety, fatigue, sleep disturbance, and social role domains. These domains are scored on a T-score metric, with a mean of 50 normalized to the general US population and an SD of 10. For Patient-Reported Outcomes Measurement Information System (PROMIS) physical function, and social role, higher scores indicate better health, while for the other PROMIS domains lower scores indicate better health. PROMIS was developed through an National Institutes of Health (NIH) initiative to improve outcome assessment and effectiveness. They provide a set of reliable, well-established, and validated self-reported psychometric measures that evaluate and monitor the physical, mental and social health from a participant’s perspective. It has been tested on a wide range of populations with chronic conditions, including LBDs.
Covariates

Finally, we also collected at baseline, relevant information on demographics, smoking status, employment, medical and social history.

Statistical analysis

Data were described using descriptive statistics such as frequency (per cent) for categorical variables and mean (SD) for continuous variables. Pearson correlation (r) was used to evaluate the association between motion features and PROMIS measures for the two cohorts. The strengths of these associations were interpreted as follows: 0.1≤r<0.3, 0.3≤r<0.5, and r≥0.5 indicated weak, moderate and strong correlations. In addition, t-tests were used to compare between the motion performances of healthy controls to patients with LBP. Finally, multiple regression analysis was used to assess whether motion differences between cohorts were influenced by other factors. All statistical analyses were conducted using JMP V.16.0 (SAS Institute) A p<0.05 was considered statistically significant.

RESULTS

Baseline cohort characteristics

A total of 50 healthy controls (24 males and 26 females) and 50 patients with LBP (24 males and 26 females) were assessed for eligibility and enrolled into the study. Mean age with SD was 51.6±10.6 years for healthy controls and 50.7±9.3 years for patients with LBP, respectively. Mean pain intensity with SD for patients with LBP was 6.2±2.6.

The majority of participants in the healthy cohort were married or in a domestic partnership compared with participants in the patient cohort (72% vs 56%). Similarly, 82% of the healthy cohort were employed compared with 54% in the patient cohort. In addition, approximately 92% of the healthy controls were non-smokers compared with 74% in the patient cohort. We found that the mean body mass index (BMI) was significantly lower for healthy controls compared with patients (26.6±4.3 vs 32.5±7.9, p<0.05). However, we found that BMI did not significantly (p>0.05) influence differences in motion between cohorts across the different planes. Finally, across all the PROs, we found significant differences between the cohorts.

Table 1 shows general baseline characteristics of healthy control and patient cohorts.

Functional motion characteristics

In general, patients with LBP exhibited significantly decreased (p<0.05) functional motions compared with healthy controls. For this data, no difference was observed in the functional motion of males versus female. Table 2 highlights the differences in motion features between the two cohorts following the functional motion test. Significant differences were found in axial ROM (healthy controls: mean=59.4°±13.2°, and LBP patients: mean=48.3°±12.4°, p<0.0001), lateral ROM (healthy controls: mean=62.5°±14.8°, and LBP patients: mean=44.9°±12.8°, p<0.0001), and sagittal ROM (healthy controls: mean=41.6°±14.0°, and LBP patients: mean=34.7°±12.0°, p=0.01), respectively. Overall, we found that lateral ROM showed the highest difference, with a 28% reduction for patients compared with healthy cohort. Figure 4 highlights the mean ROM across axial, lateral and sagittal planes for males and females within the cohorts.

For dynamic motion features (velocities and accelerations), we found significantly higher mean values for healthy controls than LBP patients across all planes. Specifically, we found significant differences in axial velocity (healthy controls: mean=294.8°/s±113.4°/s, vs LBP patients: mean=148.1°/s±59.1°/s, p<0.0001), lateral velocity (healthy controls: mean=126.9°/s±62.5°/s, p<0.0001), and sagittal velocity (healthy controls: mean=211.5°/s±73.1°/s vs LBP patients: mean=148.1°/s±59.1°/s, p<0.0001), respectively. Figure 5 shows mean velocity across planes for both sexes in healthy controls and patients with LBP. Unlike for ROM, we found that axial velocity of healthy controls was 49.7% higher than patients. In examining accelerations, we also found similar trends with significant differences in axial acceleration (healthy controls: mean=2095.6°/s²±1022.8°/s², vs LBP patients: mean=928.9°/s²±475.3°/s², p<0.0001), lateral acceleration (healthy controls: mean=1182.5°/s²±545.4°/s² vs LBP patients: mean=534.9°/s²±307.5°/s², p<0.0001), and sagittal acceleration (healthy controls: mean=1455.2°/s²±602.3°/s² vs; mean=872.3°/s²±514.2°/s², p<0.0001), respectively. Figure 6 shows mean acceleration across axial, lateral and sagittal planes for healthy controls and patients. Similar to velocity, we found that axial acceleration for healthy controls was 53.7% higher than patients with LBP. Overall, the magnitude of the difference between healthy controls and patients were considerably higher for velocity and accelerations than ROM.

Correlations between motion features and PROs

In examining the association between motion features and PROs, we found statistically significant weak to moderate correlation...
Original research

(p=0.05) between the following measures in the two cohorts. For the healthy control cohort, in the axial plane, we found that axial ROM significantly correlated with PROMIS Pain interference (r=−0.4, p=0.012) and physical function (r=0.4, p=0.005). In the lateral plane, lateral ROM showed positive correlation with physical function (r=0.4, p=0.013) only. For higher-order motion features, we found negative correlation between axial velocity and PROMIS pain interference (r=−0.3, p=0.031). In addition, axial velocity showed positive correlation with physical function (r=−0.4, p=0.014). Similarly, in the lateral plane, lateral velocity significantly correlated with PROMIS pain interference (r=−0.4, p=0.0035) and physical function (r=0.4, p=0.0016). In the sagittal plane, we found moderate correlations between sagittal velocity and PROMIS pain interference (r=−0.3, p=0.03) only. In examining the correlation between PROs and accelerations, we found that axial acceleration only correlated with PROMIS physical function (r=0.3, p=0.025); lateral acceleration showed significant correlations with pain interference (r=−0.3, p=0.026), and physical function (r=0.4, p=0.008); and sagittal acceleration showed moderate positive correlation with PROMIS social roles (r=0.4, p=0.007). No significant correlations (p>0.05) were observed between any motion feature and PROMIS domains for sleep disturbance, depression and anxiety, respectively. Figure 7 shows correlations between motion features and PROs for healthy controls.

In exploring associations in the LBP patient cohort, in the axial plane, we found significant weak to moderate correlation between axial ROM and PROMIS pain intensity (r=−0.4, p=0.003), while no significant correlations were found between other axial motion features and PROs. In the lateral plane, we found significant correlation between lateral ROM and PROMIS pain intensity (r=−0.4, p=0.009). In addition, we found that lateral velocity was significantly correlated with PROMIS pain intensity (r=−0.3, p=0.002), pain interference (r=−0.4, p=0.01), physical function (r=0.4, p=0.002), fatigue (r=0.3, p=0.05), and social roles (r=0.3, p=0.025); and lateral acceleration was significantly correlated with PROMIS Pain interference (r=−0.4, p=0.012), physical function (r=0.4, p=0.003), and fatigue (r=0.3, p=0.048). Finally, in the sagittal plane, we found that sagittal velocity showed significant correlations with PROMIS pain interference (r=−0.3, p=0.0049), physical function (r=0.4, p=0.004), and social roles (r=0.3, p=0.048); and sagittal acceleration showed significant correlation with PROMIS pain interference (r=−0.3, p=0.027), and physical function (r=0.4, p=0.003). Similar to our control cohort, we observed no significant correlations (p>0.05) between motion features and PROMIS domains for sleep disturbance, depression and anxiety respectively for patients with LBP. Figure 8 shows correlations between motion features and PROs for patients.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Motion characteristics summarized as mean ROM, velocity and acceleration extracted from functional motion assessments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Motion features</td>
<td>Controls</td>
</tr>
<tr>
<td></td>
<td>Mean (SD); count (%)</td>
</tr>
<tr>
<td><strong>Axial plane</strong></td>
<td></td>
</tr>
<tr>
<td>ROM</td>
<td>59.44 (13.2) 48.30 (12.4)</td>
</tr>
<tr>
<td>Velocity</td>
<td>294.83 (113.4) 148.10 (59.1)</td>
</tr>
<tr>
<td>Acceleration</td>
<td>2095.61 (1022.8) 928.88 (475.3)</td>
</tr>
<tr>
<td><strong>Lateral plane</strong></td>
<td></td>
</tr>
<tr>
<td>ROM</td>
<td>62.52 (14.8) 44.99 (12.8)</td>
</tr>
<tr>
<td>Velocity</td>
<td>203.74 (65.2) 117.10 (48.1)</td>
</tr>
<tr>
<td>Acceleration</td>
<td>1182.45 (545.4) 534.99 (307.5)</td>
</tr>
<tr>
<td><strong>Sagittal plane</strong></td>
<td></td>
</tr>
<tr>
<td>ROM</td>
<td>41.56 (14.0) 34.72 (12.0)</td>
</tr>
<tr>
<td>Velocity</td>
<td>211.54 (73.1) 126.95 (62.5)</td>
</tr>
<tr>
<td>Acceleration</td>
<td>1455.17 (602.3) 872.25 (514.2)</td>
</tr>
</tbody>
</table>

* t-test was used to compare the motion features of controls to patients. ROM, range of motion.
DISCUSSION
In this study, we examined the functional motion differences between healthy controls and patients with LBP using a novel spine health platform. The platform leverages the use of wearable motion sensors to provide an objective assessment of functional spine status. It facilitates collection and automated processing of both motion (kinematic) features and biopsychosocial metrics in one centralized system. Our findings demonstrated statistically significant differences in motion features between healthy and patient cohorts across anatomical planes. These results also indicated that the magnitude of these differences were more pronounced in higher order motion features such as velocities and accelerations than ROM. In addition, we found the BMI did not significantly influence the differences in motion between the cohorts. Furthermore, we also found weak to moderate correlations between motion features and certain PROs. This suggests that motion features and PROs might be measuring two very different components of the LBP experience. Finally, given the lack of objective metrics to better support clinical decision-making in evaluating treatment effects, our study highlights the potential use of a standardized functional motion assessment to quantify low back impairment and serve as potential endpoints.

Figure 5  Mean velocity across axial, lateral and sagittal planes for healthy controls and patients with LBP. LBP, low back pain.

Figure 6  Mean acceleration across axial, lateral and sagittal planes for healthy controls and patients with LBP. LBP, low back pain.
for chronic LBP treatments. Further prospective studies are needed to fully demonstrate potential use of this platform for decision support in spine care.

In general, the LBP patient cohort had diminished functional motions (ROM, velocity and acceleration values) compared with healthy controls (matched for age and sex). These findings support those of Marras et al. and other comparable research studies, where differences were observed between healthy controls and patients. However, in contrast to our results, Marras et al observed lower magnitudes in acceleration values across planes. This may be due to differing measurement techniques. In our study, we found that trunk motion in the axial and lateral planes for patients were significantly lower than healthy controls. Furthermore, we found >50% reduction in both axial and lateral accelerations compared with healthy controls. Similarly, we found >40% reduction in both axial and lateral velocity. The clinical implications of this are the potential ability to further phenotype patients and identify novel endpoints to inform treatment decisions.

Our study investigated the utility of wearable motion sensor-derived trunk kinematics to evaluate function in a clinical setting. Our results suggested that a weak to moderate correlation exists between motion features and PRO scores. Specifically, we found that motion features in the lateral plane had moderate correlations with patient-reported pain intensity, pain interference, physical function, fatigue, and social role scores. In the axial

---

**Figure 7** Correlation map between Motion features and PROs for healthy controls. Correlations were classified as weak relationship (0.1≤r<0.3), moderate relationship (0.3≤r<0.5), and strong relationship (r≥0.5). Overall, we found statistically significant (p<0.05) weak to moderate correlations between some motion features and the following PROMIS domains—pain intensity, pain interference, physical function and social role; while other PROMIS domains—sleep disturbance, depression and anxiety, showed no significant correlation (p>0.05) with any motion feature. PROMIS, Patient-Reported Outcomes Measurement Information System; PROs, Patient-Reported Outcomes; ROM, range of motion.
plane, only axial ROM had a moderate correlation with pain intensity. In the sagittal plane, we found only sagittal velocity and acceleration had significant correlations with some PROs. These findings were comparable to other studies that explored the association between spine kinematics especially ROM and PROs. For instance, Laird et al. found that high pain intensity was associated with low ROM. Similarly, Nattrass et al. also found ROM to be weakly correlated to Oswestry Disability Index. Overall, although, we found significant correlations between motion features and PROs, it is important to note that these results had <50% variance in common. The implication of our results is that while motion features are associated with dimensions of pain, function, fatigue and social roles, they are also distinct and assesses a uniquely different dimension of functional health compared with PROs. This is not surprising given the subjective nature of PRO measurements as compared with the more objective kinematics metrics. Thus, the integration of quantitative measures of motion to augment PROs has the potential to enhance our understanding of the disease, and improve patient recovery assessment. However, further prospective studies with much larger databases are warranted to validate these relationships, and determine whether these objective endpoints can inform treatment effects and improve patient outcomes.

Our study also has several limitations. First, our study population was a convenience sample and not representative of a...
diverse population. Second, the cross-sectional study design limited its ability to inform longitudinal changes. Third, while unintentional, this study did not have older patients over the age of 65 years. Finally, given that the study was conducted at a single institution, the findings may not be generalizable to larger population.

CONCLUSION
In conclusion, there has been a tremendous need for access to objective and actionable biosignal/biosensor metrics to better understand causal mechanisms that lead to LBDs, enhance clinical decision-making and improve long-term outcomes. The spine health platform described in this paper facilitates central access to novel digital functional biomarkers from wearable motion sensors along with a holistic array of biosignal/biosensor measures from patient-reported outcomes in one unified environment. It leverages modern technologies in cloud-computing, wearable sensors, artificial intelligence, machine learning and web applications to reliably collect, analyze and visualize actionable data. Our study demonstrated its utility in differentiating healthy controls and patients. Access to this collective information enables objective assessment of patients with chronic LBP that are responders and non-responders to treatment, monitor disease trajectories and treatment effectiveness, predict outcomes and facilitate personalized medicine. Collectively, this technology has the potential to shift clinical practice paradigms, improve patient outcomes, enhance care efficiency, and reduce costs.

Acknowledgements
The authors would like to acknowledge the following individuals who have provided operational support and have been integral to our study: Lindsay Hanes, Angela Emerson, Alison Wandling, Sarah Grim, Melissa Bahr, Marissa Werner, Lucas Unver, Emily Huber, Johnny Mckeown and Cole Buchanan. In addition, we would also like to acknowledge the Back Pain Consortium (BACPAC) Research Program. The BACPAC program is administered by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). Contributors
All authors made significant contributions to this research, have read and agreed to the published version of the manuscript. The following are specific contributions by each author: Conceptualization, PM, JD, GK and AA; methodology, PM, JD, GK, AA and WSM; methodology, PM, JD, GK, AA, DMB, JV, MT, NH, SK, TW, and WSM; software, JD, and AA; validation, JD, AA, and WSM; formal analysis, PM, JD, GK, AA, and WSM; investigation, PM, JD, GK, AA and WSM; resources; DMB, IV, NH, SK, TW, and WSM; data curation, DMB, JV, NH, SK, and TW; writing—original draft preparation, PM, JD, GK, and WSM; writing—review and editing, PM, JD, GK, DB, MT, and WSM; visualization, DB, SK, NH, MT, and JV; supervision, WM, and TW; project administration, PM, JD and WSM; funding acquisition, TW and WSM. PM is the guarantor of this article.

Funding
This research was funded in part by National Institutes of Health (NIH) through the NIH HEAL Initiative under award numbers 1U2AR076729-01, 4UH3AR076729-02, 1U2AR076730-01, 3UH3AR076729-0251 and 3UH3AR076729-0252. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health or its NIH HEAL Initiative. Additionally, this research was also supported by a variety of funds from Defense Health Agency (DHA) under contract numbers - W81XWH-20-19; W81XWH-20-21; W81XWH-20-22; and W81XWH-20-23. Competing interests
None declared.

Patient consent for publication
Not applicable.

Ethics approval
The study protocol (IRB protocol #: 2020H0250) was approved by the Ohio State University’s Institutional Review Board (IRB).

Provenance and peer review
Not commissioned; externally peer reviewed.

Data availability statement
Data are available on reasonable request.

Supplemental material
This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

ORCID iDs
Prasath Mageswaran http://orcid.org/0000-0003-0015-B812
Jayesh Vallabh http://orcid.org/0000-0002-3429-1028

REFERENCES
Original research


