Assessing Disability and Functional Outcome Measurements using Spinal-Specific Wearables and Telehealth to Improve Spinal Patient Care

Ram Haddas[1], Paul Rubery[1], Emmanuel Menga[1], Justin Jablonski[1], Varun Puvanesarajah[1], Yair Barzilay[2]
[1]University of Rochester Medical Center, Rochester, NY, USA, [2]Shaare Zedek Medical Center, Jerusalem, Israel
Ram_Haddas@URMC.Rochester.edu

Disclosures: R. Haddas: 3B; Medtronic. 5; Scoliosis Research Society, Medtronic, The Cervical Spine Research Society, Aspen Medical Products. P. Rubery: None. E. Menga: None. J. Jablonski: None. V. Puvanesarajah: None. Y. Barzilay: None.

INTRODUCTION: Spine surgeons often report their clinical outcomes using validated instruments, including patient-reported pain, functional disability, radiographic parameters, depression indices, pain medication intake, and physical function. Analysis of these various outcome measures provides a robust assessment of a patient's disease severity, intervention effectiveness, and rehabilitation progress. Sequelae like adjacent segment pathologies are increasingly being recognized as multifaceted challenges that push the boundaries of what can be inferred solely from static radiographic analysis and stand to benefit greatly from increased understanding of changes in spinal alignment during activity. Individuals with spinal injuries and disease naturally come to avoid behaviors and postures that provoke pain. Such activity restriction, while minimizing increases in pain and opioid intake, can have significant, adverse physical, emotional, and cognitive consequences when pain becomes chronic. Healthcare reforms that demand quantitative outcomes and technical innovations have emphasized the use of Disability & Functional Outcome Measurements (DFOMs) for spinal conditions and interventions. Virtual healthcare has become increasingly important following the COVID-19 pandemic, and wearable medical devices have proven to be a useful adjunct. Wearable devices are both cost-effective and broadly available to the general population and can provide a longitudinal representation of the general health and mobility of the wearer, as opposed to time-dependent and subjective patient-reported outcome measures (PROMs) or in-office physical assessments. Thus, given the advancement of wearable technology, broad adoption of commercial devices by the general public, and the growing demand from consumers to take control of their health, the healthcare providers is now primed to formally incorporate evidence-based wearable device-mediated telehealth into standards of care. Therefore, the purposes of this study were (1) To evaluate the feasibility and compliances of telehealth using home wearable DFOMs in spine patients, (2) To identify wearable-based key DFOMs that are clinically meaningful, and (3) To associate wearable DFOMs with common PROMs.

METHODS: After receiving institutional review board approval from an academic medical center in north America, we prospectively recruited patients with common degenerative spinal conditions who were deemed surgical candidates in a multi-center cohort study. Twenty lumbar degenerative surgical candidates (LD) and 15 healthy controls were fitted with a small wearable sensor (30 x 44 x 8mm, weight: 12 grams) placed on T1 spinous process for 3 days. The sensor is able to assess free-living physical activity along with trunk kinematics in the patients' home-based environment. The raw sensor data (i.e. triaxial accelerometer readings), processed data (i.e. sensor orientation in Euler angles), and select algorithm-generated DFOMs (i.e. time spent sitting, walking, standing, sitting, etc.) was generated and hosted in a secure cloud repository. Then, a retrospective balance, sway and gait analyses were performed using the sensor data. Patient-reported outcome measures information system (PROMIS) and Opioids consumption were collected during the 3 days periods. Outcome measures were wearable-based DFOMs and PROMIS. One-way Analysis of Variance (ANOVA) was used to compare patients' function pre- surgery to the control group. Moreover, Pearson's R correlation was used to define the relationship between DFMOs to PROMs scores, psychological status, and Opioids consumption.

RESULTS: The wearable was successfully able to measure DFOMs by detecting free-living physical activity (walking, standing, sitting, laying down, and driving times in addition to trunk 3-dimensional range of motion; Figure 1). Moreover, the wearable was able to detect patient sway, balance effort, and gait parameters. LD patients presented with lower free-living physical function along with reduced trunk kinematics (walking: 4.7%, standing: 11.6%, sitting: 25.3%, and laying down: 41.7% of the day, trunk flexion: 15.8°) at their home-based environment in comparison to controls (walking: 8.9%, standing: 19.1%, sitting: 17.1%, and laying down: 36.2% of the day, trunk flexion: 10.3°; $p<0.05$). Moreover, LD patients demonstrated reduced balance and gait with increased sway (balance effort: 25.6°, walking: 0.8 m/s, sway: sagittal: 7.9°, coronal: 7.2°) compared to controls balance effort: 14.6°, walking: 1.0 m/s, sway: sagittal: 5.8°, coronal: 3.2°; Figure 2). Strong correlations were found between wearable DFOMs to the PROMIS scores ($r2 >0.55$, $p<0.05$).

DISCUSSION: Wearable technologies have the potential to revolutionize healthcare through continuous data collection in patients' home-based environments. This type of device enables objective data to be collected longitudinally while patients perform functional tasks relevant to their daily lives, something that is usually difficult to obtain postoperatively for spine surgery patients. As wearable technology becomes more prevalent in orthopedics, healthcare costs may be reduced and patient outcomes may improve. A combination of DFOMs gathered using a wearable device in conjunction with PROMs and radiographic measurements, will provide a comprehensive evaluation of spine patients' health and assist physicians with patient-specific treatment decision making. Furthermore, these objective data, which are unique to each patient in their home environment, may allow a customized definition of return to work and potentially mitigate risk exposure. Remote monitoring of patient data is extremely promising since it can be wirelessly sent and made available to physicians, enabling real-time preventative interventions and reducing healthcare costs.

SIGNIFICANCE/CLINICAL RELEVANCE: Wearable technology is an emerging technology sector that can provide valuable health information to patients and surgeons. A combination of DFOMs using a wearable device with PROMIS and radiographic measurements may provide a more comprehensive evaluation of a spine patient's health and assist the physician in better treatment decision-making, a customized definition of return to work, and mitigate risk exposure.

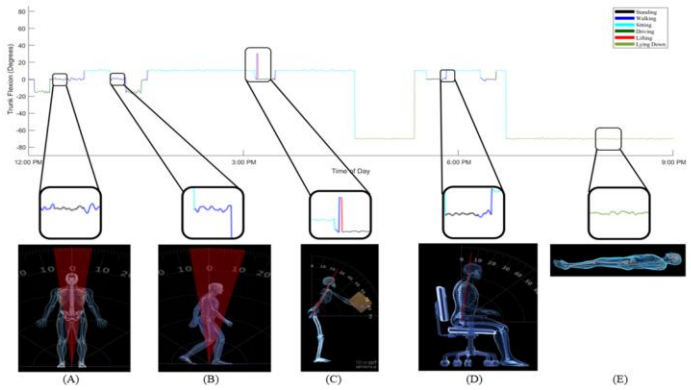

Figure 1. Aanalysis of trunk motion based on the predict activity data of the wearable sensor. *A. Balance/Cone of Economy Analysis; B. Gait Analysis, C. Lifting Analysis, D. Sitting Analysis, E. Sleeping Analysis.*

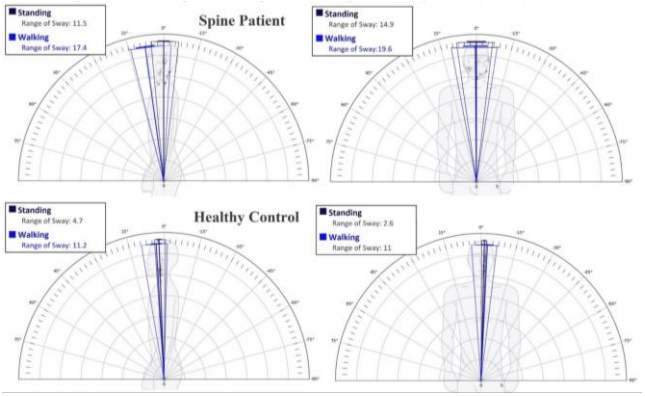

Figure 2. Standing and Walking Cone of Economy Dimension and Balance Effort in the Sagittal (Left) and Coronal (Right) Planes for a Representative Spine Patient (Top) and Healthy Control (Bottom).