New Approaches to Measuring Health Outcomes - Leveraging a Gaming Platform

Clinical trials employ a variety of approaches to measure the health status of patients and changes in their health due to treatment. In many therapy areas, subjective ratings made by the patient (patient-reported outcome measures – PROs) or by a clinician (clinician-reported outcome measures – ClinROs) are used to measure status or change over time. Patient-reported outcomes measures, such as a daily symptom diary or a quality of life questionnaire, importantly measure the perspective of the patient regarding the effects of treatment, and in some cases (e.g. pain assessment) may be the only way to assess outcomes. ClinROs include measures of symptoms through direct observation of the patient. For example, depression symptoms and severity may be rated by a trained clinician following a structured interview using the Hamilton Depression Rating Scale. A further clinical outcome assessment, and the one on which we focus in this article, is the performance outcome (PerfO). This is a measurement by a healthcare professional based upon observation of a task performed by the patient. In some cases, these PerfOs are measured using subjective assessments. Quite a number of subjective measurement scales are used in clinical trials to assess balance, movement or mobility based on observation of the patient conducting a specified movement or activity. Some examples of these are detailed in Table 1, although many others exist.

Scale	Measurement
Fugl-Meyer Assessment	Arm, hand and shoulder movement
Tinetti Balance Assessment	Balance and walking movement
Berg Functional Balance Scale	Balance and movement
Dynamic Gait Index	Gait features
Hauser Ambulation Index	Walking ability

Table 1. Examples of common subjective performance outcomes used in today's clinical trials

Subjective ratings (e.g. assessing the patient using a verbal response scale) are not very sensitive to detecting small improvements, and different investigators may rate patients differently based upon their interpretation of the scale requirements. For this reason, it is sometimes difficult to make measurements that are sensitive enough to detect treatment-related changes and are able to conclusively show treatment effects when they exist. In addition, using investigator observation, it is less likely that detailed or subtle aspects of movement and mobility can be recorded. In this article we describe a simple proof of concept developed by ICON's Product Innovation team to leverage the Microsoft Xbox gaming platform to generate objective measures as a possible alternative to subjective PerfO instruments.

Current Use of Gaming Platforms in Health and Wellness

A number of gaming systems enable motion-based gaming experiences and utilise a depth camera to track movements to enable players to engage with video game content. These same platforms can be leveraged to track movement in a range of healthcare and wellness applications. In particular, the Microsoft Kinect sensor, a component of the Xbox gaming system, has been particularly successful in enabling the development of health applications due to the ability of the Kinect to operate on a PC platform and the utility of its associated Software Development Kit (SDK) to facilitate the development of applications that track body movements.

In particular, there is a growing body of applications leveraging Microsoft Kinect in developing interactive solutions for rehabilitation, including novel ways of engaging patients in regular exercise regimens and solutions to ensure that exercises are performed correctly for optimal outcomes. Examples include rehabilitation solutions in the areas of stroke (1), Parkinson's disease (2), multiple sclerosis (3) and cerebral palsy (4). These applications use the skeletal tracking module within the Kinect SDK, which enables the 3D position of 26 body joints to be tracked over time without the need for the patient to wear sensors, special clothing or special markers (Figure 1).

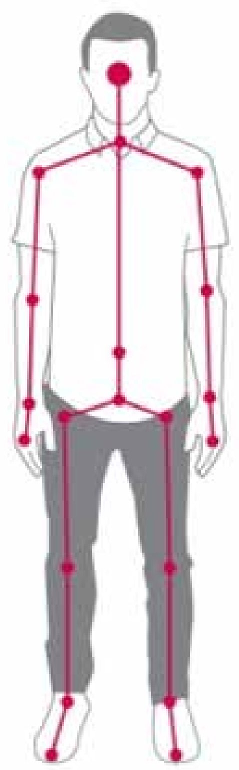

Figure 1. Body joint skeletal tracking using Microsoft Kinect.

This same capability can be used to record and measure aspects of movement during performance tasks completed by the patient. As a proof of concept, we have developed a simple application that runs on a Windows 8.0 or 10.0 PC or laptop with a USB 3.0 connection, along with an Xbox Kinect 2.0 sensor and a Kinect for Windows adapter. This equipment is inexpensive (approximately $150 for a sensor and adapter) facilitating its use for in-clinic assessments within large-scale clinical trials.

Proof of Concept – Measurement of Shoulder Range of Motion

Using the 3D coordinates of a number of body joints, it is possible to measure the range of motion associated with the upper extremity movement, in particular shoulder range of motion. This could be of value in assessment of adhesive capsulitis treatment or measuring changes in upper arm movement in stroke patients, for example. In this application, we used the position of shoulder, elbow, wrist and spine to calculate range of motion angles during a sequence of movement tasks performed by the patient (Figure 2).

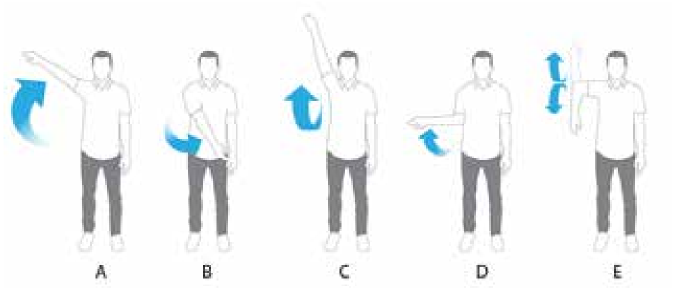

Figure 2. Performance tasks in the Microsoft Kinect application for shoulder range of motion

Using formulae for the angles between vectors, we were able to convert joint coordinates to calculate the angles achieved during these performance tasks, and also to record the path of motion traced during the conduct of the tasks (Figure 3). The angle of abduction (A) we calculated from the maximal angle achieved between upper arm and spine while raising the straight arm above the head along the coronal plane. We calculated adduction by reversing this motion as far as possible in the opposite direction, across the body (B). Similarly, we calculated forward flexion by requesting the subject to raise their arm above the head away from the body along the sagittal plane (C). We calculated rotation by asking subjects to move their wrist away from the body along the transverse plane while holding the elbow close to the body (D), assessing the maximal angle achieved between forearm and upper arm. Finally, we estimated angles of internal and external rotation in abduction (E) while the subject kept their elbow at shoulder height and rotated by moving the forearm up (external rotation) and down (internal rotation).

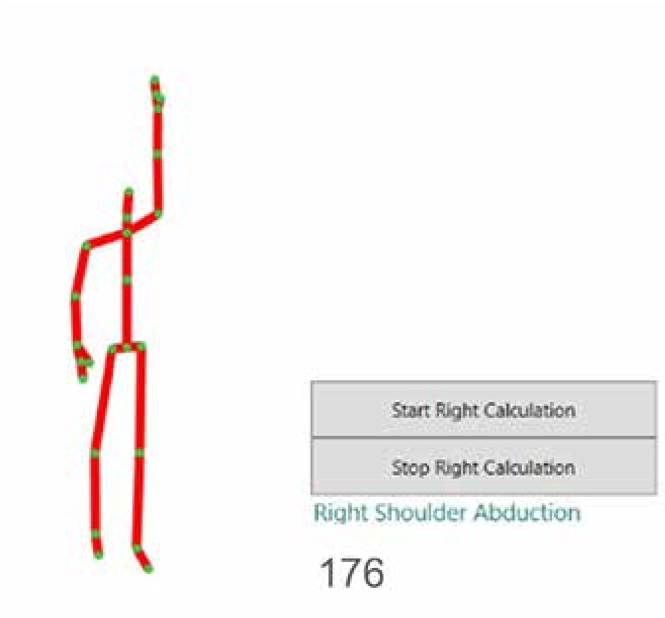

Figure 3. Software application for shoulder range of motion assessment

These tests are performed with the patient standing around 2 m from the Kinect sensor (Figure 4).

Figure 4. Measuring abduction angle using the Microsoft Kinect application (subject is author DW)

Initial tests comparing angles measured by the Kinect system to those using a goniometer have suggested good concordance in measurements, although the tracking of joints was seen to be less reliable during the adduction task. Moving the arm across the body appeared to make it difficult for the depth camera algorithms to assess the position of the elbow and wrist accurately. However, the approach has shown promise in the other range of motion assessments studied and has indicated good utility for the conduct and instrumentation of these simple in-clinic performance tests.

The Potential of Gaming Platforms to Measure Health Outcomes

While more testing is needed to assess the accuracy and utility of the application we have developed to measure shoulder range of motion, it is clear that the Microsoft Kinect platform offers a versatile and low-cost approach to measure novel health outcomes. This may add significant value and utility to clinical drug development, in particular in replacing conventional subjective measures. The potential of this approach will be dependent on being able to develop simple performance tasks that can be completed and measured within the depth range (0.5 to 4.5 m) and field of vision of the depth camera.

Potential tests may include a number of approaches, such as:

- Assessing gait parameters in a short walking test where patients walk in a straight line towards the sensor, or navigate simple obstacles
- Measuring upper and lower body functional mobility
- Detecting and measuring involuntary movements during still standing or sitting tasks
- Measuring body sway during standing or balancing tasks.

One nice property of the Kinect approach is that it provides a full picture of the entire body while the patient performs the requested movement(s). This provides a richer picture than some alternative instrumented approaches, such as using a body-worn accelerometer. Further testing will determine which tasks are best suited to the capabilities of Microsoft Kinect to provide accurate measures of interest. The sampling rate and resolution of the camera, for example, may limit its ability to measure finer or more rapid movements.

Conclusions

Our study has indicated good proof of concept. While more work is needed to understand and assess the accuracy and precision of the Kinect sensor, initial findings have been promising.

The use of games platforms such as Microsoft Kinect to measure clinical outcomes offers a versatile, easy to use and low-cost approach that may have value in generating health outcome measures during in-clinic performance tasks. Of course, additional work on the validity and reliability of data collected in this way would be required for use in clinical trials. In addition, an assessment of the interpretability of outcomes derived – such as understanding the minimal clinically important difference in measurements observed – will be important when utilising this approach, as with any new approach to the measurement of health outcomes. As seen in the area of rehabilitation, however, gaming platforms offer a novel and potentially engaging approach that may enable researchers to understand more, and characterise more precisely, the effects of treatment in a wide range of disease indications. We anticipate further research and development activity seeking novel application of these platforms in the field of clinical research and clinical trials.

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