CLOUD-CONNECTED SPINAL BRACE SENSOR TO DETERMINE WEAR COMPLIANCE

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INTRODUCTION

Lumbar and thoracolumbar bracing have been prescribed by clinicians for non-operative and post-operative spine patients for decades. iLink™ is an electronic module that detects if a patient is wearing their brace and records and uploads that information to a secure website through the user's smartphone. With the sensors on-board, the iLink module also measures a patient's posture and mobility. Time spent upright versus recumbent and ambulation are keys to avoiding postoperative complications due to inactivity for post-surgical patients. The iLink battery life lasts a minimum of 12 weeks to account for a typical patient's prescribed brace use. Each day the iLink measures and records up to 1,440 data points for each category of wearing compliance, posture, and mobility.

DETECTION

The purpose of embedding iLink into a spinal brace is to monitor wearing compliance, therefore human discernment is accomplished with a capacitive sensor at a maximum distance of 5 millimeters away from the user. Detection and position testing was confirmed by testing the sensor against a target object at 0, 2.5, and 5mm away, as shown in Figure 1 below.

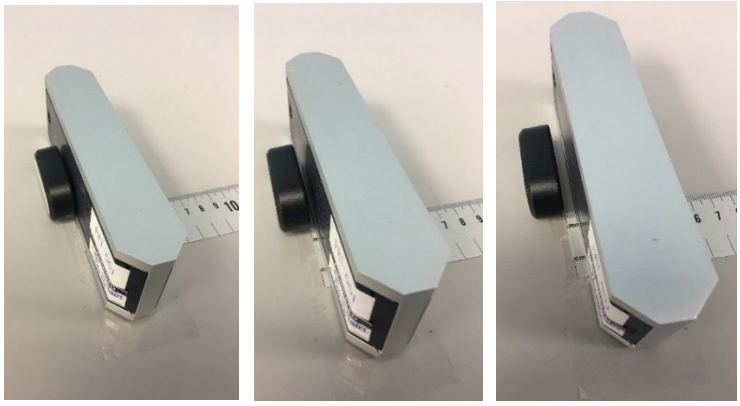

Figure 1. Target object 0mm, 2.5mm, and 5mm, respectively away from iLink

Discernment between human and inanimate objects is also essential to determine when the user is wearing the brace and when they take it off. Detection was then tested by placing the brace on a person, folded on itself to check against self-detection, face down on a wooden table, and face down on carpet.

Figure 2. Position of brace for calibration and to test against self-detection, face down on carpet and table, respectively

ANGULAR POSITION

Post-operatively, it is beneficial for the patient to be upright for a prescribed amount of time each day. Upright position is measured as being greater than 45 degrees, which would be the difference between reclining in a chair and sitting upright. Angular position was performed by placing the sensor lid against a digital protractor for object detection and angle measurement and determine that the iLink app detects the sensor as upright between 45±5 degrees and shown in Figure 3 below.

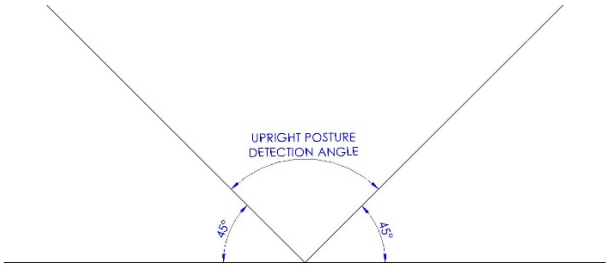

Figure 3. Upright angle detection of iLink

MOBILITY

Post-operatively, mobility of the patient is monitored to help assess patient activity each day, because avoiding complications is contingent on patient activity. The iLink measures mobility using a 3-axis accelerometer when acceleration is above a preset threshold. The graph of the 3-axes is shown in Figure 4 in the screen capture of the iLink application. Mobility was verified by taping an object onto the iLink for constant detection and taped onto a vibration table, shown in Figure 4. Each sensor was tested for two 15-minute periods with 5 minutes of rest in between on the vibration table to confirm that the sensor can detect movement/ mobility.

Figure 4. Live mobility data using 3-axis accelerometer and vibration table

COMMUNICATION

When setting up the iLink for use, the time of day which the iLink will communicate/sync with the Android device is configured. Once this time is set, the sensor and Android device will automatically turn on each day at that time to sync. The syncing process completes in 15 minutes or less. If the two devices do not connect to each other, they will connect the next time the iLink is within Bluetooth range during the sync time without losing any data. Once connected, the data is then uploaded onto the iLink web portal, as the device has adequate memory to store up to 12 weeks of data.

For communication testing, an object was taped to the sensors for constant detection and secured in an upright position. Once the sensors were configured with the iLink app, they were scheduled to sync with their respective devices 24-hours later. When syncing occurred, the sensors remained one meter away from the Android devices, as shown in Figure 5 to confirm communication over distance.

The Android application allows for the patient and the surgeon to easily monitor progress and compliance. Figure 7 shows a screen capture of wear and posture of a sensor used during the verification testing.

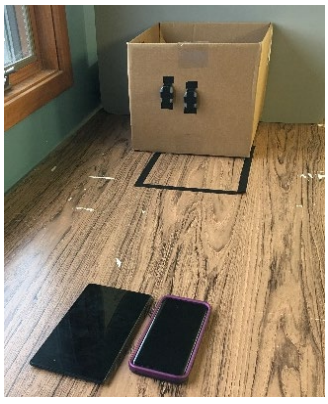

Figure 5. Android devices set 1m from iLink sensors for syncing

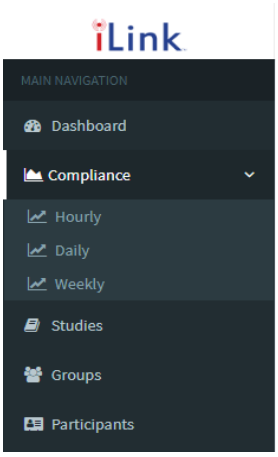

Figure 6. iLink web portal features

Figure 7. Weekly wear and Posture Compliance on Android application.

The web portal allows the surgeon to view compliance data for all patients at the hourly, daily, and weekly levels (Figure 6). They can also export the data from the secure website to a csv file for graphing, as shown in Figure 8.

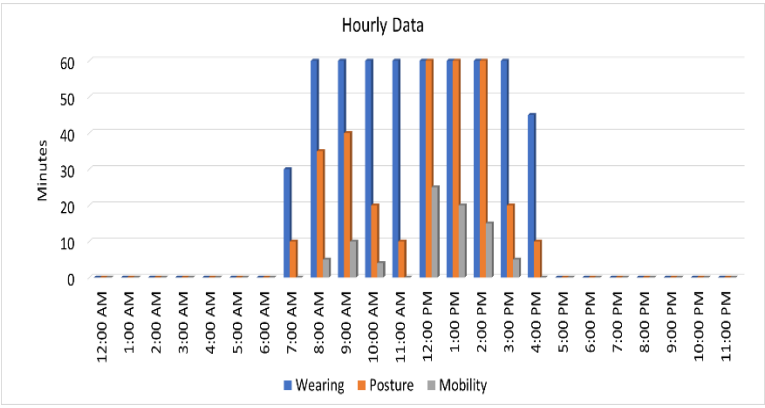

Figure 8. Exported data representing wearing compliance, posture, and mobility by hour

CONCLUSION

The iLink has demonstrated the ability to accurately measure and record wearing, posture, and mobility data and connect to Android devices. The data that the iLink provides will promote patient engagement and caregiver feedback to improve compliance and therefore maximize brace efficacy and enhance patient outcomes.