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Validity and Reliability of a Novel Wearable Sensor System for Documenting Clinical Outcome Measure of the Knee in Healthy Individuals – A Piolet Study

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Abstract:- Background: In orthopaedics today, sensing technology is routinely used. It is most frequently established in perioperative care and fundamental studies of human mobility. Given that modern wearable technology is capable of monitoring and diagnosing capabilities, this technology could assist in addressing some of the issues the healthcare industry encounters. Numerous patients experience knee joint issues during the course of their lifetime. Fitknees® is a wireless motion sensor-based system that assesses the clinical, functional and subjective measurements of chronic knee injury patients. Aim of Study: The objective of this clinical study was to determine the validity and reliability of Fitknees® against the currently used clinical methods like goniometry, timed tests and distance calculations during various assessment tests in healthy population. To test the validity and reliability of fitknees for range of motion, extension lag, proprioception and static and dynamic balance and stair climbing. Methods: The study included 10 healthy adults without knee pain. The individuals aged between 18 years and above. Tests for validity were performed concurrently on the same testing sessions. Reliability tests were performed by subjects within 48 hours between sessions. Results: The knee outcomes measured by Fitknees® were range of motion (ROM), extension lag, proprioception, static balance, dynamic balance and staircase climbing. Fitknees® was found to provide greater accuracy and better ability to detect minimum changes in patients for most measures, in comparison to conventional assessment methods. Reliability was also high for all outcome measures, except mobility with shows significance with p value < 0. 005.Conclusion: The results of the study indicate that the Fitknees® is a reliable and conditionally valid wearable sensor system for quantifying clinical outcomes of the knee.

Keywords:- *Motion sensor, knee outcome, progress tracking, treatment documentation, biomechanical data, remote healthcare, experienced clinician assessment*

I. INTRODUCTION

In orthopaedics today, sensing technology is routinely used. It is most frequently established in perioperative care and fundamental studies of human mobility. Given that modern wearable technology is capable of monitoring and diagnosing capabilities, this technology could assist in addressing some of the issues the healthcare industry encounters. Numerous patients experience knee joint issues during the course of their lifetime[17]. There is a significant gap in communication between the clinician and the patient, due to which the clinician is unable to retain the patient for physiotherapy[1]. It has been scientifically proven that evidence-based physiotherapy provides manifold over manual physiotherapy practices because it provides concrete data to the patient. Evidence-based physiotherapy helps in setting clear, quantifiable goals in rehabilitation and thereby delivers visible results. Going by statistics, about 80% of the patients never come back for a second consultation with the physiotherapist and 70% of the patients who opt for physiotherapy drop out midway (usually once the pain subsides)[2].

Evidence based physiotherapy has been scientifically proven to deliver far superior results to patients in comparison to conventional physiotherapy methods. Most widely used evidence-based assessment machines like camera-based gait laboratories, isokinetic dynamometers and balance measuring machines are currently very bulky and expensive and thus only available to international level athletes and in bigger hospitals.

There are a small number of studies where deep learning models have been trained to predict knee joint angular kinematics for walking from IMU training data collected mostly from healthy people. It has been seen that Wearable sensor based systems provide data driven reports that improve the physical self-awareness of patients, which allows them to be more receptive to treatment, avoid injury and pursue faster time to recovery [5,6].

An Inertial measurement unit (IMU) is a package of sensors which typically measures acceleration using an accelerometer and angular velocity using a gyroscope, and are augmented with magnetic field measurement to aid in direction estimation. These systems are used in medical equipment like intelligent patient beds, surgical robots, angiography applications etc[5].

Fitknees® provides comprehensive clinical assessments in one device while being portable and affordable. The outcome measures captured include clinical tests like active range of motion, extension lag, proprioception double and single leg static balance, muscle strength of quadriceps and hamstrings, timed up and go dynamic balance, functional tests-6-minute walk test & stair climbing.

II. METHOD

The study was conducted in a multispeciality hospital. The participants were aged between 6-14 years both male and female. The sample size of 10 participants (5 male and 5 female) without history of knee pain were asked to attend two session for reliability testing which included measures of Range of Motion (ROM), Muscle Strength. Proprioception, Balance & Functional tests. All the participants were given enough information about the use of the fitknees device. All tests were performed by an experienced clinician. Tests for validity were performed concurrently on the same testing session. Reliability tests were performed with a minimum of 48 hours between the test sessions. The standard measures used were goniometer, 2D analysis.

A. Test Protocol for Individual Outcome Measures

➤ *Fitknees® System:*

The device was strapped on to both legs, of the patient around the thighs (mid-thigh) and lateral shanks (midway between the Tibia & lateral malleoli) (refer Figure 2). The Fitknees® software on the tablet is enabled with a built-in voice command feature . Each test started with a verbal command to the patient coordinated with a press on the start tab in the Fitknees® application. All tests were performed for both the legs alternatively with exact same procedures. All tests were demonstrated and a trial was allowed before the actual test commenced.

- *Mobility Flexion*

Fitknees® was tested against a long arm goniometer for validity testing. Tests were performed by a senior physiotherapist with the subjects lying down in supine position on a patient bed. Maximum knee flexion was measured as the ability to bring the heel as close to the hips as possible. (Figure 1(A))

- *Mobility: Extension Deficit*

Fitknees® was tested against 2D video analysis with angle marked as the angular measurement between the long axis of the femur and the tibia. Maximum active knee extension performed in a seated position without substitutions the patient bed or leaning back) was measured. (Figure 1(B))

- *Proprioception*

The knee joint was moved slowly with the subject’s eyes closed, by applying slow force through a thick foam pad at the subject’s heel. The subject was instructed to give verbal feedback as soon as they felt slight movement at their knee joint. Maximum angular displacement was captured by Fitknees® and compared against 2D video analysis, without substitutions (lifting thigh off the patient bed or leaning back). (Figure 1(C))

- *Static Balance Test:*

For timed static balance tests, subjects maintained four different standing positions with incremental levels of balance challenges for 10 seconds. The 4 stages include double leg stand, stand in semi tandem, tandem and single leg stand. The test was repeated for both the legs. Tests were stopped at the first indication of loss of balance for a position. A stopwatch was used as the gold standard and a score of 1.

Was awarded to the subject, every time they passed one stage. (Figure 1(D))

- *Dynamic Balance Test*

Fitknees® software enabled with a voice command feature was tested against stopwatch. The subject was instructed to stand up and , walk 3 meters at a brisk pace and walk back to the initial position. The test finished when the subject assumed the sitting position again. The test was stopped with a coordinated “Stop” button on the Fitknees® tablet and simultaneously turning off the stopwatch. (Figure 1(E))

- *Stair Climbing Test*

Fitknees® software enabled with a voice command feature was tested against a stopwatch. A standard stair that had 12 steps each measuring 8-inch high was used for all the tests. Upon the clinician’s command, the patient climbed upstairs and downstairs as fast as he/she could. Once both the feet of the patient touched the ground/floor, the clinician tapped the ‘Stop’ button on the tablet and switched off the stopwatch, simultaneously. (Figure 1(F))

Fig 1 Study Participants Undergoing Data Collection for: (A) Range of Motion (B) Extension Deficit (C) Proprioception (D) Static Balance (E) Dynamic Balance (Timed Up and Go) (F) Staircase

III. RESULTS

➢ *Validity*

A high degree of validity was found between the Fitknees® and the corresponding gold standard measure for all the measures (Table 1). The average measure was 0.97 with all values being statistically significant (p=0.001). From the Bland Altman test (Figure 1), the mean difference for angular tests, including flexion, extension deficit and proprioception ranged from just over 0.00 to -1.95 degrees. The mean difference for all timed tests, including static balance, dynamic balance and stair climbing tests, ranged from 0 to 0.15 seconds.In case of healthy subjects, proprioception and stair climbing tests have at least one outlier, while all remaining test results lie within the line of agreement (LOA).

Table 1 Corresponding Gold Standard Measure for all the Measures

Outcome measures	ICC with 95%CI	Significance
Mobility Flexion	0.99 (0.97 - 0.99)	P=0.001
Mobility Extension Lag	0.99 (0.98 - 1.0)	P=0.001
Proprioception	0.98 (0.91 - 0.99)	P=0.001
Static Balance	0.82 (0.03 - 0.97)	P=0.03
Dynamic Balance (Total)	0.99 (0.97 - 1.0)	P=0.001
Stair Climbing	1.0 (1.0 - 1.0)	P=0.001

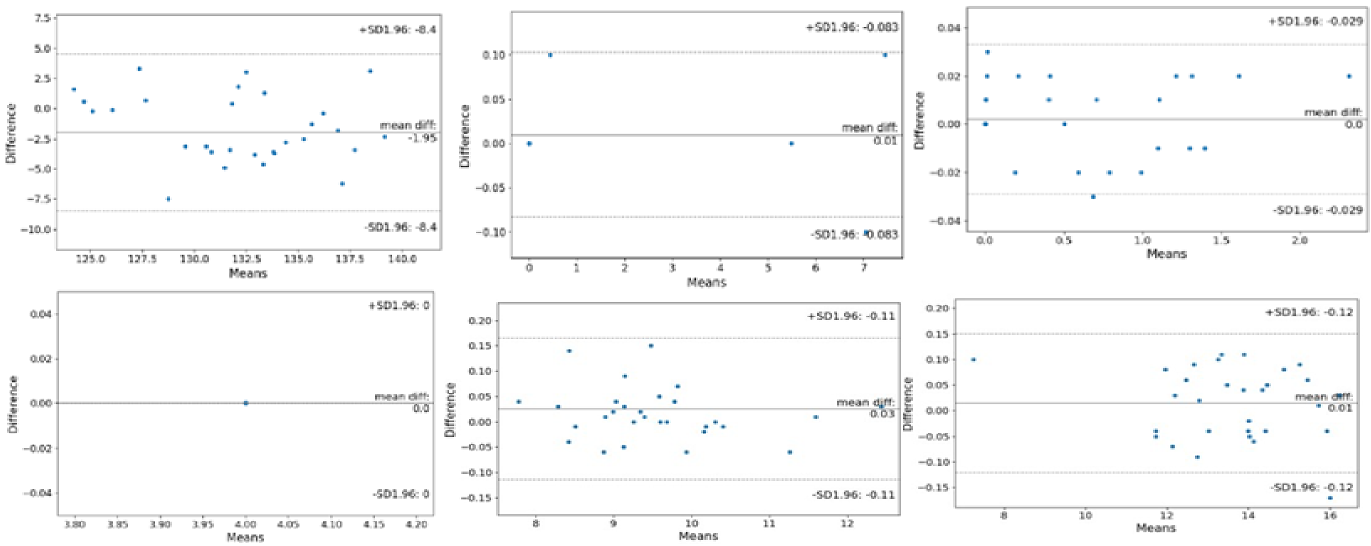

Fig 1 The Bland Altman Test

➢ *Relaibility*

All measures were performed for healthy subjects bilaterally. The mean of right and left knee was taken for analysis because no significant side to side difference was observed in any outcome measures for the healthy population.

A high degree of reliability was found between the Fitknees® and the corresponding gold standard measure for all the measures (Table 2).

Among all the subject categories, mobility was least reliable, with the SEM measure as 1.573 for 95% confidence interval. All other outcome measures including extension lag, proprioception, static balance, dynamic balance and stair climbing are less than 0.024, indicating high test- retest reliability.

All measures for coefficient of covariance (CV) under 0.1 were considered good. All measures for standard error measurement (SEM) under 0.1 were considered good.

Table 2 Test - Retest Reliability Results For Healthy Subjects

Outcome Measures	CV with 95% CI	SEM with 95% CI
Mobility Flexion	0.011 (-0.01 - 0.34)	1.573 (-1.45 - 4.71)
Mobility Extension Lag	0.016 (-0.01 - 0.05)	0.024 (-0.006 - 0.09)
Proprioception	0.143 (-0.16 - 0.39)	0.006 (-0.006 - 0.01)
Static Balance	0	0
Dynamic Balance (Total)	0.002 (-0.002 - 0.008)	0.023 (-0.11 - 0.07)
Stair Climbing	0.002 (-0.002 - 0.007)	0.31-0.15 - 0.09)

IV. DISCUSSION

Multi sensor systems are predominantly used for gait analysis and capture varied parameters. While they are good for research purposes, clinical adaptation of this system is a challenge due to the cost of equipment and time to set up and conduct each assessment. Fitknees® is a 4-sensor system that is designed to be easily adaptable in clinical practice. Reliable and valid measurement of knee outcome measures has wide research and clinical implications. Accurate documentation is important to empower patients to participate in planning and implementation of their physiotherapy treatment[9]. Motion sensors provide meaningful and actionable insights into the recovery of patients, while overcoming the limitations of static gait laboratories to assess force distribution on the knees. Creating a framework to develop an inexpensive, accurate and portable joint motion capturing system for diagnostics purposes in a clinician's office by to et aL fortifies the feasibility and necessity of sensor based assessments at point of care[11].

The validity results mainly comprise two findings:

- First, the validity of Fitknees® healthy individual are significant for most parameters.
- Second, Fitknees® measured the minimally detectable changes in outcome measures more accurately than the existing gold standard practices

Test-retest reliability was performed on healthy subjects by an experienced assessor since it is a novel device and required familiarisation of the tech, to minimize the errors due to lack of experience, avoid protocol deviation and maintain consistency.

In the context of clinical practice, this represents the highest levels of validity for measurements across all the chronic conditions of the knee irrespective of the age, sex and duration of the symptoms. The gold standards used for comparison reflects the routine clinical practice. However there are arguments about validity, minimum detectable change in measure and the measurement errors of the gold standard measures also[13,14,15]. Yet it can be concluded that despite any deficits in human errors that are possible with any clinical measurements, the Fitknees® device measures are accurate, repeatable, reproducible, and comparable to existing gold standards. However the minimum detectable change is better with Fitknees® (As opposed to goniometer, stopwatch and 2D video analysis, which are subjected to human errors).

V. CONCLUSION

Fitknees® is shown to be a reliable and valid system for documenting clinical outcome measures in non injured populations for knee joint. While accurate and better, the relevance of minimum detectable change of a sensor based motion capture system needs to be compared against the clinically relevant change that is routinely documented by existing gold standard measures.

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LIMITATIONS

Gold standard for most outcome measures are not standardized and established, thereby limiting the inference of validity for Fitknees® system.

Fitknees validity and relaibility can be found in knee injury patients.

Current validity can be performed because Fitknees® is a new technology that requires operational expertise & familiarisation. Furthermore, it was clinically observed that junior practitioners were unable to reliably capture gold standard readings from goniometers, stopwatch and inch tapes as accurately as a senior practitioner.

The sample size used to test the reproducibility (n=10) was relatively smaller making it susceptible to a sampling bias, However the ICC values were as reported in the literature and no abnormal findings were found.

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