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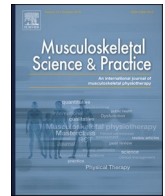
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Technical and measurement report

Reliability and validity of the Microgate Gyko for measuring range of motion of the low back

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ABSTRACT

Background: The aim of this study was to test the inter- and intrarater reliability and the concurrent validity of the Gyko Microgate for the assessment of lumbar range of motion.**Methods:** A cross-sectional study was carried out with two groups of healthy participants. The first group, consisting of 91 subjects, was tested to determine the inter- and intrarater reliability. Concurrent validity was assessed with comparisons with an optical motion system (Vicon) in a second group of 20 subjects. Lumbar range of motion in flexion, extension, left and right lateral flexion were performed. Intraclass correlation coefficient (ICC) was calculated for both analyses. Measurement error was calculated with standard error of the measurement (SEM), smallest detectable change (SDC) and Limits of Agreement (LoA). ICCs were considered good when $ICC \geq 0.80$ and excellent with $ICC \geq 0.90$.**Results:** Interrater reliability was good to excellent with ICCs ranging from 0.82 to 0.94. Intrarater reliability was good to excellent with ICCs ranging from 0.84 to 0.95. Concurrent validity was excellent with ICCs varying from 0.90 to 0.95. LoA were highest in interrater reliability and smallest in concurrent validity. SEM ranged from 2.2 to 4.0° in lateral flexion left and flexion respectively. SDC varied from 6.1 to 11.1°.**Conclusion:** Gyko has good inter- and intrarater reliability and excellent concurrent validity compared to the optical motion system for lumbar range of motion. Gyko may be considered as objective measure to measure range of motion for clinical purposes, however trials with patients are currently lacking.

1. Background

Low back pain (LBP) is a common disease that occurs in all age groups (Hoy et al., 2014). Worldwide, LBP ranks the first position in the years lived with disability list out of 289 impairments (Vos et al., 2012). LBP results in significant levels of disability and restrictions on daily activity, including work (Hartvigsen et al., 2018; Kuijer et al., 2006). To decrease this burden, clinicians, amongst others physiotherapists, aim to restore normal function and relieve pain to the patient, based on information derived from questionnaires, subjective and physical examinations. During the physical examinations mechanical factors of the lumbar spine such as range of motion (RoM) will be obtained. A decrease in lumbar region movement in the sagittal plane has been displayed in LBP patients (Hernandez et al., 2017). To obtain a better insight in the clinically relevant outcomes within RoM tests, quantifying

measurements have been recommended in LBP (Van Dillen et al., 2007). In practice, quantification of movement is not yet incorporated within regular care and clinical assessment of LBP relies mainly on self-report questionnaires. These self-reports depend on the patient's perception and psychosocial status, including pain, anxiety and catastrophizing (Smeets et al., 2011). There are several techniques to measure RoM. The most simple way is to perform a standardized clinical test (i.e. maximum flexion) and measure the differences between marked bony segments (Akinpelu and Adeyemi, 1989). Objective analogue instruments used for RoM are inclino- or goniometers (Mayer et al., 1984). While these instruments are the cheapest options, these instruments require a strict protocol to minimize common errors, such as the estimation of the point of rotation and maintaining the instrument at this location (Milanese et al., 2014).

More comprehensive and complex automated measures comprise

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opto-electric measures, including Elite (BTS, bioengineering, Milan, Italy), Vicon (Vismara et al., 2010) or Kinescan/IBV (Sanchez-Zuriaga et al., 2011). A disadvantage of these systems, however, is their usability and availability in clinical practice. The equipment is expensive, time consuming, and demands high expertise in data processing. Therefore, these measures can be considered not-cost effective and not applicable for routine measurement. Portable and wearable sensors may live up to these demands. A recent systematic review identified 22 studies using wearable technology for spine movement (Papi et al., 2017). Most frequently, accelerometers, often combined with gyroscopes and magnetometers were used. While many of these studies report on validity, the technology is considered in a more or less experimental phase, extensive use in physiotherapy practice is still limited.

The Gyko from Microgate may live up to the demands, portable and wearable. Recently the Gyko has been introduced in sports sciences (Arede et al., 2019; Lesinski et al., 2016). These two studies showed that the Gyko is affordable, portable and suitable wearable device (Arede et al., 2019; Lesinski et al., 2016). However, its reliability and validity are unknown for measuring RoM of the lumbar back. The aim of the present study is to examine the inter- and intrarater reliability, measurement error and concurrent validity of the Microgate Gyko for the measurement of RoM of the lumbar back in healthy subjects.

2. Methods

2.1. Study design

A single-centre, non-randomized cross sectional study was performed.

2.2. Subjects

Subjects were recruited based on convenience sampling from networks at XX University of Applied Sciences in the Eastern part of XXX. Inclusion criteria were subjects between 18 and 65 years of age and providing informed consent. Exclusion criteria were LBP, presence of red flags and lumbosacral radicular syndrome, pregnancy, previous back surgery, psychiatric diagnosis and a body mass index >30. The study was part of regular education at XXX University of Applied Sciences. The local ethics committee decided that formal approval was not necessary because subject burden was low and the study was of low risk.

2.3. Raters

All measures were performed by physiotherapy students in their third year within a research class. The Gyko claims to be an easy to use instrument, therefore these relatively inexperienced students were trained in examination of the standardized protocol by two experienced practitioners and researchers (one PhD student (AH) and her supervisor (RS) during a 1-h training.

2.4. Procedures

Prior to the measurements, all subjects were instructed in the test procedures and signed informed consent. Subjects were practiced the protocol before the measurements took place, to guarantee the protocol was performed as intended. Both validity and reliability were measured in the sagittal (flexion/extension) and frontal (lateral flexion) plane of the lumbar spine. Subjects started all movements from an upright neutral standing position. For flexion, subjects were instructed to bend their spine as far as possible, while keeping knees extended. For extension, subjects extended their spine as far as possible, while keeping their hip in a neutral standing position (hip and pelvic movement were minimalized). For lateral flexion, subjects were instructed to bend their spine sideward as far as possible with arms held besides the body, without compensatory flexion or rotation. All measurements were

repeated three times. During the reliability measurement, subjects were marked at the thoracic lumbar junction, then equipped with the Gyko sensor at the thoracic lumbar junction. The first measurement was administered by rater 1. After this measurement the Gyko was fully removed and repositioned and measured by rater 2. Subsequently, the procedure was repeated by rater 1 to calculate intrarater reliability. During the validity measurement, the protocol deviated a bit from the reliability measurements. While going through the validity measurement test set up, it appeared that when making a full flexion, some markers of the Vicon system became invisible. Therefore, it was chosen to make a sub maximal flexion. At the start of the validity measurement, Gyko and the Vicon body markers were secured to the subjects. The Gyko was placed at T5, which was higher compared to the reliability measurements, to reflect the standardized plug in gait model from Vicon, which works with markers at C7 and T10 represent the trunk segment. Therefore placing the Gyko in between, on T5, represents the most optimal position. Figure 1 This validated situation provides a good representation of all the body segments and thus range of motion. The (validity) measurements with both systems were performed simultaneously.

2.5. Measurements

2.5.1. Vicon

An optical motion capture system was used as gold standard (Windolf et al., 2008). The reliability is good to excellent (ICC values: $r > 0.75$)¹⁷. The system uses eight infrared cameras (Vicon Vantage V5, 350 fps, Vicon Motion Systems, Ltd., Oxford, UK) to register reflective body markers. The use of eight cameras were sufficient to reach comparable accuracy (Eichelberger et al., 2016). The markers were placed based on the Plug-in Gait full body model. The software (Vicon Nexus) calculates the angles of movement of the subjects, by reconstructing the reflective body markers to a digital stick figure. From the stick figure RoM was calculated. The procedure of calculating the RoM of the spine is based on the manual of Vicon, of the Thorax Angle was used.

2.5.2. Gyko

RoM was measured with an inertial sensor system Gyko (dimensions: $50 \times 70 \times 20$ mm, mass: 35 g). The device is developed by Microgate (Bolzano, Italy). The hardware specification of the components of Gyko are for the accelerometer ± 2 Gravitational acceleration(G)- $\pm 16G$, the gyroscope $\pm 250^\circ$ per second ($^\circ/s$) $\pm 2000^\circ/s$ and the magnetometer $\pm 4800 \mu T$ (μT). Using Bluetooth 4.0, information is streamed to a computer. The system can be attached to an accessorized elastic belt.

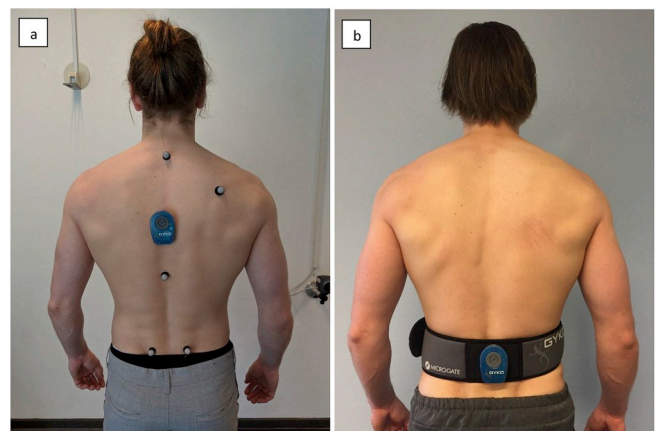


Fig. 1. These photos illustrate the positioning of the sensors used in the measurements of validity (a) and reliability (b) with Vicon and Gyko system.

2.6. Statistical analysis

Descriptive statistics were provided for each patient and data were checked for normality and missing data. Criteria for reliability and validity were made according to criteria of the Consensus-based Standards for the selection of health Measurement Instruments; COSMIN (Mokkink et al., 2010a). For both the Gyko and Vicon measurements, the maximal RoM in flexion, extension and lateral flexions were reported.

2.7. Reliability

Reliability measures relevant for the instrument are inter- and intrarater reliability. For the intrarater reliability, subjects were measured twice with a 15-min interval by the same rater. Average Intraclass Correlation Coefficients (ICCs), including 95% confidence intervals were calculated for each test.

2.8. Measurement error

To test measurement error in each test, standard error of measurement (SEM) and smallest detectable change (SDC) and Bland Altman plots to examine limits of agreement were presented (Bland and Altman, 1986). Measurements of interrater reliability were collected with repeated measures with 2 different raters during the sessions. SEM and SDC were calculated using the following formula's:

$SEM = s_x \sqrt{(1 - r_{xx})}$ (Portney and Watkins, 2009), whereas s_x is the baseline standard deviation and r_{xx} the correlation coefficient of the reliability measures. SDC was calculated using the formula: $SDC = 1.96 \times \sqrt{2} \times SEM$ (de Vet et al., 2006).

2.9. Validity

The concurrent validity of the Gyko was assessed with comparisons between the RoM assessed by the Gyko and the Vicon motion capture system. ICCs were calculated to test the correlation between both systems. 95% limits of Agreement were calculated to identify the agreement between the Gyko and Vicon. 95% of all points should lie between 1.96 standard deviations of the mean differences between devices.

For all tests, p-values < 0.05 were considered statistically significant. ICCs were interpreted as follows: ICC > 0.90 is excellent; good when ICC is 0.75–0.90, and poor to moderate when ICC < 0.75 (Portney and Watkins, 2009). All statistics were calculated with SPSS-24 (SPSS Inc. 233 South Wacker Drive, Chicago).

3. Results

3.1. Subjects

In total, 91 subjects performed the intra- and interrater study and 20 subjects performed the concurrent validity study. The data of two subjects were partly unreadable in the Vicon software analysis and were excluded for analyses. Descriptive statistics for the cohorts are presented in Table 1.

Table 1
Descriptive statistics of included subjects.

| | Reliability cohort (N = 91) Mean ± sd | Validity cohort (N = 20) Mean ± sd |
|------------------|--|---------------------------------------|
| Gender (M/F) | 33/58 | 10/10 |
| Age (years) | 24 ± 3 | 25 ± 7 |
| Body length (cm) | 182 ± 9 | 176 ± 10 |
| Body weight (kg) | 76 ± 10 | 69 ± 8 |

cm = centimeter; kg = kilogram; sd = standard deviation.

3.2. Intrarater reliability

The results of the intrarater reliability are presented in Table 2. ICC in both the axial and sagittal plane range between 0.84 and 0.95, which reflect good to excellent results. Limits of agreement (LoA) vary from −9.6–7.1° in lateral flexion to −17.8–18.0° for flexion. There were no significant differences between test and retest. Measurement error varied in SEM from 2.2 to 4.0° and SDC varied from 6.1° to 11.1° in respectively lateral flexion left and flexion.

3.3. Interrater reliability

The results of the interrater reliability are presented in Table 3. Interrater reliability ICCs varied in all 4 tests between 0.82 and 0.94, with LoA varying between −9.4 and 8.6° in lateral flexion to −19.1–19.8° in flexion. Differences between rater 1 and rater 2 were not significant. Measurement error: SEM varied from 2.4 to 4.5° and SDC varied from 6.6° to 12.4° in respectively lateral flexion left and flexion.

3.4. Concurrent validity

The concurrent validity of Gyko compared to Vicon in all the measurements have good to excellent results with ICCs > 0.80. Results are presented in Table 4.

4. Discussion

Results from this study show that both the reliability and validity are good to excellent for the studied sagittal and frontal spine movements. All raters were instructed in administering a standardized protocol for the RoM tests and received a 1-h instruction on how to use the Gyko (hardware and software) and perform a test measurement. In a previous study of the Gyko (Lesinski et al., 2016), the counter movement and squat jump height have been studied in 19 subjects and compared to other gold standards. The authors present high ICCs, reflecting good concurrent validity for jump height, however, there appeared a significant systematic bias, predominantly caused by the accessorised elastic band, that should be corrected for (Lesinski et al., 2016). With regard to measurement error, smallest detectable change in the tests varied from 6.1 to 11.1°, with the highest values in flexion and the lowest in lateral flexion. If SDC is expressed as a percentage of the mean value, all values lie between 11 and 38 percent. Especially for the extension test, a considerable measurement error was found, while flexion and lateral flexion perform well.

A particular strength of the current study was the number of subjects that were tested in the reliability study (Mokkink et al., 2010b). A limitation could be that the intrarater reliability was measured at the same day. For measurements, in which a recall bias is likely to occur, a sufficient wash out period is deemed necessary. In the Gyko, however, the data cannot be interpreted differently and subjects were kept unaware of their results. It was chosen to keep the time intervals short because the chance for recall bias is small, and the chances for inter-day variability in RoM were assumed to be more threatening. The validity cohort contained 20 persons, because data-obtaining with the Vicon system was very time consuming. The results, however, appear robust by multiple measurements in different planes. A source of bias could be the differences in measurement procedures of validity compared to reliability, however these procedures were due to the restrictions of the used Vicon system.

In this study, the Gyko was used for validation and reliability purposes only. The study was performed in a laboratory setting with healthy subjects instead of a clinical setting with LBP patients, therefore the reliability and validity of Gyko should be further examined in patient samples in clinical practice to study its exact clinical value.

Table 2
Intrarater reliability statistics (N = 91).

| Test | Test 1 | Retest 2 | Intrarater reliability | | Measurement error | | | |
|---------------------------|-------------|-------------|------------------------|-----------|-------------------|-----------|-----|------|
| | Mean ± sd | Mean ± sd | ICC | 95% ICC | LoA lower | LoA upper | SEM | SDC |
| Flexion (°) | 99.1 ± 18.2 | 98.9 ± 21.4 | 0.95 | 0.92–0.96 | –17.8 | 18.0 | 4.0 | 11.1 |
| Extension (°) | 27.7 ± 10.2 | 29.0 ± 11.1 | 0.87 | 0.80–0.91 | –15.4 | 12.9 | 3.7 | 10.2 |
| Lateral flexion left (°) | 23.9 ± 6.6 | 25.2 ± 7.1 | 0.89 | 0.83–0.92 | –9.6 | 7.1 | 2.2 | 6.1 |
| Lateral flexion right (°) | 24.0 ± 6.0 | 25.8 ± 6.8 | 0.84 | 0.76–0.90 | –10.5 | 6.8 | 2.4 | 6.6 |

° = angle in degrees; ICC=Intraclass correlation coefficient; LoA = Limits of Agreement; SEM = Standard error of the Measurement; SDC = Smallest Detectable Change; sd = standard deviation. All ICC values have p-values<0.01.

Table 3
Interrater reliability statistics (N = 91).

| Test | Rater 1; | Rater 2; | Interrater reliability | | Measurement error | | | |
|---------------------------|-------------|-------------|------------------------|-----------|-------------------|-----------|-----|------|
| | Mean ± sd | Mean ± sd | ICC | 95% ICC | LoA lower | LoA upper | SEM | SDC |
| Flexion (°) | 99.1 ± 18.2 | 98.7 ± 21.4 | 0.94 | 0.90–0.96 | –19.1 | 19.8 | 4.5 | 12.4 |
| Extension (°) | 27.7 ± 10.2 | 28.5 ± 10.4 | 0.86 | 0.79–0.91 | –15.0 | 13.4 | 3.8 | 10.6 |
| Lateral flexion left (°) | 23.9 ± 6.6 | 24.3 ± 6.8 | 0.87 | 0.80–0.92 | –9.4 | 8.6 | 2.4 | 6.6 |
| Lateral flexion right (°) | 24.0 ± 6.0 | 24.8 ± 6.5 | 0.82 | 0.73–0.88 | –10.3 | 8.7 | 2.5 | 7.1 |

° = angle in degrees; ICC=Intraclass correlation coefficient; LoA = Limits of Agreement; SEM = Standard error of the Measurement; SDC = Smallest Detectable Change; sd = standard deviation. All ICC values have p-values<0.01.

Table 4
Concurrent validity (N = 20).

| Test | Gyko; | Vicon; | Concurrent validity | | | |
|---------------------------|-------------|-------------|---------------------|-----------|-----------|-----------|
| | Mean ± sd | Mean ± sd | ICC | 95% ICC | LoA lower | LoA upper |
| Flexion (°) | 55.6 ± 13.2 | 49.3 ± 12.2 | 0.84 | 0.50–0.94 | 1.61 | 6.83 |
| Extension (°) | 29.7 ± 9.7 | 27.9 ± 7.5 | 0.96 | 0.87–0.99 | 0.38 | 3.36 |
| Lateral flexion left (°) | 38.0 ± 6.5 | 38.8 ± 6.0 | 0.91 | 0.76–0.96 | –1.78 | 0.67 |
| Lateral flexion right (°) | 39.5 ± 5.3 | 39.1 ± 5.5 | 0.91 | 0.78–0.97 | –1.03 | 0.89 |

° = angle in degrees; ICC=Intraclass correlation coefficient; LoA = Limits of Agreement; sd = standard deviation. All ICC values have p-values<0.01.

5. Conclusion

The inter- and intrarater reliability and concurrent validity of the Microgate Gyko are good to excellent for measuring sagittal and frontal spine RoM in a laboratory setting. In future studies it is recommended to investigate if the Gyko might be used clinically as an alternative measure for conventional measures of range of motion of the lumbar back.

Ethical approval

Not applicable.

Funding

Not applicable.

Declaration of competing interest

None declared.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.msksp.2019.102091>.

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