Validation studies

Functional leg length discrepancy between theories and reliable instrumental assessment: a study about newly invented NPoS system

Asmaa Mahmoud1,2
Paolo Abundo3
Luisanna Basile3
Caterina Albensi1
Morena Marasco3
Letizia Bellizzi3
Franco Galasso4
Calogero Foti1

1 Physical and Rehabilitation Medicine, Department of Clinical Sciences and Translational Medicine, “Tor Vergata” University, Rome, Italy
2 Physical medicine, Rheumatology and Rehabilitation Department, Cairo, Egypt
3 Medical Engineering Service, Polyclinic Tor Vergata, Rome, Italy
4 Baro Postural Instruments Srl Innovative Start Up, Rome, Italy

Corresponding author:
Asmaa Mahmoud
Physical and Rehabilitation Medicine, Department of Clinical Sciences and Translational Medicine, “Tor Vergata” University
00133 Rome, Italy
E-mail: mhmsma01@uniroma2.it

Summary

Background: In spite the instinct social&financial impact of Leg Length Discrepancy (LLD), controversional and conflicting results still exist regarding a reliable assessment/correction method. For proper management it’s essential to discriminate between anatomical&functional Leg Length Discrepancy (FLLD). With the newly invented NPoS (New Postural Solution), under the umbrella of the collaboration of PRM Department, Tor Vergata University with Baro Postural Instruments srl, positive results were observed in both measuring&compensating the hemi-pelvic antero-medial rotation in FLLD through personalized bilateral heel raise using two NPoS components: Foot Image System (FIS) and Postural Optimizer System (POS). This led our research interest to test the validity of NPoS as a preliminary step before evaluating its implementations in postural disorders.

Methods: After clinical evaluation, 4 subjects with FLLD have been assessed by NPoS. Over a period of 2 months, every subject was evaluated 12 times by two different operators, 48 measurements in total, results have been verified in correlation to BTS GaitLab results.

Results: Intra-Operator&inter-operator variability analysis showed statistically insignificant differences, while inter-method variability between NPoS and BTS parameters expressed a linear correlation.

Conclusion: Results suggest a significant validity of NPoS in assessment&correction of FLLD, with high degree of reproducibility with minimal operator dependency. This can be considered a base for promising clinical implications of NPoS as a reliable cost effective postural assessment/corrective tool.

Level of evidence: V.

KEY WORDS: hemi-pelvic rotation, lower limb inequality, new postural solution, personalized heel raise, postural assessment, functional leg length discrepancy, anatomic leg length discrepancy.

Introduction

Evaluation, prevention and treatment of postural disorders represent an open question in musculoskeletal dysfunction. Leg length discrepancy (LLD) is commonly recognized within this category. In spite of the multiplicity and the instinct social and financial impact of health problems associated with LLD, surprisingly controversial and conflicting results still exist regarding a reliable clinical method of assessment and correction.

It is essential to discriminate between anatomical and apparent or Functional Leg Length Discrepancy (FLLD) for proper management and correction. FLLD can be described as a unilateral asymmetry of the lower extremity without any concomitant shortening of the osseous components of the lower limb1. The exact prevalence of LLD is unknown; it varies, according to some Authors, between 65 and 90% of the general population2. However the existence of FLLD and its negative impact on biomechanical health is not in doubt it is a fact.

As suggested in literature FLLD may result from adaptive shortening of soft tissues, joint contractures, ligamentous laxity, or axial malalignments3, 4; one of mechanisms suggested is abnormal foot mechanics, such as excessive asymmetric pronation; when foot
Pronation is accompanied by decreased longitudinal arch height compared to the contralateral side, resulting in a functionally shorter limb ipsilaterally. Others suggested that it may be caused by torsion occurring at the pelvis, knee, foot and ankle joints, and left-right imbalance due to fixed occupational position, daily life habits or poor posture. The extent to which these techniques accommodate for a LLD has not been clearly defined, this may explain why so far no corrective tool for FLLD proved to be effective. Generally speaking posture is still not an easy subject to study or to manage; could be because postural assessments are still scientifically inaccurate like tape measure, or expensive like Magnetic Resonance Imaging (MRI), or involve risks of radiation as X-ray. With the newly invented NPoS (New Postural Solution), under the umbrella of the collaboration between Physical and Rehabilitation Medicine Department, “Tor Vergata” University with the Baro Postural Instruments (BPI), positive results were observed in both measuring and compensating the hemi-pelvic antero-medial rotation in subjects with FLLD, compensation was through personalized bilateral heel raise using the two NPoS components; Foot Image System (FIS) that measures the height of the raises required and Postural Optimizer System (POS); the podometric test that evaluate the corrective modifications acquired with custom raises in the frontal and the sagittal planes.

Hypothesis: Considering Therapeutic attempts many articles addressed placing a heel lift in a shoe as a general treatment of choice for leg length discrepancy. But if this is not an anatomical leg length discrepancy, then a unilateral heel lift is not an applicable treatment option. On the other hand other studies concerned with FLLD, usually involved treatment focusing on the hip, pelvis, and/or lower back, rather than the leg. The “NPoS” in FLLD is a suggested solution to correct pelvic asymmetry, to enhance femoral internal rotation and to equalize distribution of body weight between both feet using personalized bilateral heel raise measured by FIS component of NPoS system; NPoS as a corrective solution hypothetically reduces the stress caused by improper position of the femoral head inside the acetabulum, helps to eliminate musculoskeletal deficiencies and improves patient treatment outcomes. For diagnostic purposes the innovation was designed to: analyze the non-weight bearing feet, to measure the personalized heel height (“NPoS Correction”), to investigate the forefoot-to-rearfoot plantar pressure ratio; POS component performs a comparative analysis of patients’ data both barefoot and with simulated personalized heels height to measure the achieved correction.

Objective: The purpose of this investigation was to establish the intra-operator and inter-operator reliability of NPoS in FLLD assessment and compensation by the personalized bilateral heel raise as a basic step before evaluating its clinical implementations in postural disorders, and to compare its values with traditional BTS GaitLab measurements.

Methods

Students from “Tor Vergata” University population volunteered for this research that was performed as a descriptive laboratory study included 4 subjects out of 10 volunteers with FLLD; 2 males and 2 females of 24 years as an average age. The protocol of this study followed the international ethical standards as described by Padulo et al., 2013 and all participants before they agreed to participate were given oral and written information and signed a consent to use their data. The 10 volunteers passed through two phases; 1st history taking and clinical assessment, to determine their eligibility to participate in the study. Four subjects out of 10, participated in the 2nd phase of instrumental assessment. The 6 subjects were excluded for various causes; absence of FLLD, associated anatomical LLD more than 2 cm, recent history of musculoskeletal accident or surgery, concomitant musculoskeletal deformity of severe degree.

Clinical assessment

Recruitment and full clinical evaluation took place in Physical Medicine and Rehabilitation Department, “Tor Vergata” University in Rome, Italy, as follows:

1. Registration of personal data, and history taking including history of surgical interventions or accidents compromising back or lower limb function in the last year.
2. Physical examination, to ensure presence of FLLD, to detect musculoskeletal posture malalignment, to exclude anatomical discrepancy and to record segmental measurements; every single measurement was estimated bilaterally and repeated 3 times, the average was calculated to minimize bias.

The measurements taken:

A. In standing position

- To exclude anatomical LLD: with feet together and fully extended knees, the distance of right and left anterior-superior iliac spine (ASIS) from the mid-line was measured. If ASISs are not at the same distance from the midline, or differs in height on the horizontal plane, measuring of lower limb segments for the presence of a real discrepancy was necessary (Tab. I).

- To confirm functional LLD: beside using the conventional bubble inclinometer to determine the presence of pelvic tilt, the volunteer was tested in the same position as in forward bending test, as follows; with feet together and knees fully extended, the subject was asked to flex the trunk forward over the hip joints, the physician holds the GT with the thumb resting on PSIS bilaterally and asks the subject to assume the standing position again. If, during this movement, physician’s thumb at one side is driven in a vertical direction at a level different than the other side, an apparent shortening is suspected (Fig. 1). In order to esti-
mate the value of this apparent shortening, the following body segments were measured (Tab. II).

B. In supine position
Assessment of external and internal rotation of hip joints and distances from ASIS and from Umbilicus to MM were measured bilaterally.

Instrumental assessment
Out of 10 volunteers, 4 subjects were included to be assessed by NPoS and BTS at Baro Postural Instruments Laboratories, according to the following protocols.

Table I. Measurements carried out to estimate the value of an anatomical LLD.

<table>
<thead>
<tr>
<th>Land marks of distances measured in both lower limbs</th>
</tr>
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<tbody>
<tr>
<td>Greater trochanter (GT) – Medial Tibial Condyle</td>
</tr>
<tr>
<td>GT- Lateral Tibial condyle</td>
</tr>
<tr>
<td>Lateral Tibial Condyle – Lateral Malleolus</td>
</tr>
<tr>
<td>Posterior Superior Iliac Spine (PSIS) – midline</td>
</tr>
<tr>
<td>Difference in height between left and right PSIS</td>
</tr>
</tbody>
</table>

Table II. Measurements carried out to estimate the apparent LLD.

<table>
<thead>
<tr>
<th>Land marks of distances measured in both lower limbs</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASIS - midline</td>
</tr>
<tr>
<td>Difference in height between ASIS of both sides</td>
</tr>
<tr>
<td>ASIS – medial malleolus (MM)</td>
</tr>
<tr>
<td>ASIS – ground</td>
</tr>
<tr>
<td>Umbilicus – medial malleolus (MM)</td>
</tr>
<tr>
<td>Umbilicus – ground</td>
</tr>
<tr>
<td>GT – ground (with trunk extended)</td>
</tr>
<tr>
<td>GT – ground (with trunk flexed)</td>
</tr>
<tr>
<td>PSIS – ground</td>
</tr>
<tr>
<td>PSIS – midline</td>
</tr>
<tr>
<td>Difference in height between PSIS</td>
</tr>
</tbody>
</table>

ASIS, Anterior Superior Iliac Spine; MM, Medial Malleolus; GT, Greater Trochanter; PSIS, Posterior Superior Iliac Spine.

Figure 1 A, B. A) The subject was asked to flex the trunk forward over the hip joints, while the physician holds the GT with the thumb resting on PSIS bilaterally. B) The subject was asked to assume the standing position again.
NPoS protocol

First step was to identify the personalized height of the bilateral heel raises using FIS component, then, corrections acquired were evaluated with a second static baropodometric assessment using POS component. In this section the instrumentation used and the manner of execution of different tests are presented in details.

1. FIS system (Foot Image System)

This system allowed us to identify the height of bilateral heel lift in a personalized manner. The innovation introduced by this system gives the possibility to image foot out of load without additional soft tissue and external stress, in order to estimate the correction required more accurately.

FIS system is composed of a moving base with a stand upraise-vertically-away from this base, its end is connected with a system that enables rotation of an arm attached to a camera (Fig. 2). The camera is able to take images of foot from anterior, medial, posterior views. The right position of the camera is ensured by an adjustable chassis (Fig. 3).

Through software developed with visual assessment the operator can:
- lead remotely the arm’s rotation by sending specific control instructions;
- lead remotely images’ acquisition;
- detect the personalized height of bilateral heels.

The personalized height for the required heel lift is measured on foot corresponds to the hip without limited rotation (where the limb apparently is longer). First, the subject is placed in prone position with the knee flexed at 90°, the foot suspended with relaxed muscles. The operator puts two spherical markers: one at the center of the calcaneus, the other in correspondence to the third metatarsal head (Fig. 4).

The stand runs the camera transversely along a circular trajectory, after running of 90° it stops automatically to acquire foot image, the image is viewed on a computer interfaced with the system by Wifi. At the end of complete circle, 4 images results and from medial view the value of personalized height of heel raises can be determined.

By selecting points in which markers are placed, the software identifies these points and calculates the height of a right triangle in which the hypotenuse is the line joining
the 2 markers. This triangle is constructed by a series of steps implemented by the software; the markers are generally placed on different frontal planes. So, a scale factor is calculated in order to consider the two different planes placement. This factor is the ratio between:

- the radius of the marker measured on the obtained images (expressed in video unit) varies according to the plane in which the marker is placed;
- the known radius of the sphere expressed in mm.

Then the distance between the farther marker and the line passing through the marker closer to the operator is calculated. That distance is multiplied by the scale factor to obtain the height of the triangle. The other 3 images obtained by FIS system can be used by physician to evaluate any other parameters of interest (Fig. 5).
2. **POS system (Postural Optimized System)**

The second system consists of a resistive pedometer that rests on a structure composed of two parts: anterior fixed part and posterior movable part. The latter, from orders given by a control panel, can be raised till reach the heel’s height previously evaluated by the FIS system. The baropodometric platform is composed by a layer with a conductive powder: compression generates an electric current with intensity proportional to the pressure exerted. The current scrolls on a resistance and establishes a voltage drop whose value is then converted into a pressure level by an 8-bit A/D converter. In addition to the baropodometric platform, POS system is composed of an infrared camera placed in front of the system, which detects the images of the subject and shows the spatial position of markers (placed as described below). The baropodometric platform and the camera are hyper-linked to the computer by a USB connection. On the anterior fixed part of the platform, in correspondence of the mid-line, there are two markers placed for the system’s calibration.

In the second phase of the experimental protocol the operator places 4 markers on specific landmarks: on left and right anterior-superior iliac spines and on left and right greater trochanter.

The instrumental examination continues with two subsequent steps:
- data acquisition with heels simulation (with posterior part raised);
- data acquisition without heels simulation (with posterior part flat).

During the transition between the two steps the subject maintains the same position in the first acquisition the moving part of platform is raised by an amount equal to the personalized heel height calculated by FIS system, then the subject rises above the platform and assumes a standing position for few seconds (static re-evaluation), placing the metatarsal heads along the line that divides the steady part from the movable part. POS system, at this point, through developed software on Visual Basis, integrates the information of the baropodometric examination with the acquisition of marker’s spatial position, in order to give the following information (Fig. 6 a, b):
- the body weight distribution on the sole of feet;
- the support polygon obtained around the sole of feet and the position of its geometric center;
- the identification of postural attitude through the position of center of gravity and center of pressure;
- the marker’s spatial position; from this markers a trapezius is built, from which the following parameters are expressed:
  - distance between right and left ASIS and mid-line;
  - distance between right and left GT and mid-line.
- distance between the axis passing through the geometric center and the axis passing through center of gravity (inter-axle).

In the second acquisition, while patient is yet placed on the platform, the posterior movable part is reset to remove the heels’ simulation. The analyses described above are repeated to compare acquired data with and without heels.

**BTS System Protocol**

Results obtained by FIS and POS components were verified by BTS system. BTS is a certified and commercialized optoelectronic system composed of six infrared cameras that capture the signal from markers applied on the subject, two digital cameras, two force platforms and a 8- surface EMG channels.

Same test required by POS system was executed by BTS system, acquiring the same parameters evaluated with and without heels (Fig. 7). BTS system isn’t composed by a movable platform that is able to raise to simulate heels’ height, so heels of different heights were placed under both subject’s feet, in order to acquire data with heels.

**Data processing and analysis**

As already introduced in the preceding section, the objective of this work is to analyze the repeatability and reproducibility of the measurement obtained by the NPoS system, in order to ensure its versatility of use. A comparison was predisposed between this innovative Fis-POS system and a valid, widely used gait analysis method; the BTS system. Twelve measurements were obtained for each subject in 3 separate sessions over a period of 2 months.

In order to evaluate NPoS measurements’ dependence on operator involved in the markers’ placement procedure, the 2 different operators obtained two measurements alternatively, reporting 4 measurements in total each session.

A single measure provides for the acquisition of personalized heels’ height by FIS system and for the acquisition by POS and BTS systems of the parameters illustrated in Figure 7.

As previously described POS system provides the following distances:
- distance between right and left ASIS and the mid-line;
- distance between right and left GT and the mid-line.

These parameters are added to obtain the total distance between right and left ASIS. The same is done to obtain the distance between right and left GT.

In order to evaluate the measures’ repeatability and reproducibility, the following parameters were analyzed:
- intra-operator variability: markers were placed on the same subject by the same operator during different measurements in a session;
- inter-operator variability: markers were placed on
the same subject by 2 different operators during the same session;  
- inter-method variability: markers were placed on the same subject by the same operator and the measure is observed with 2 different methods (comparison between POS-BTS measurements);  
For data collection and management Microsoft Excel 2007 was used, while for data analysis MATLAB R2010a was used, these are in addition to the following:  
- The intra-operator variability was evaluated by the comparison between the variation coefficient percentage (CV%) of each parameter.  
- The inter-operator variability was evaluated from the differences between the averages of the values of each parameter, analyzed by the paired Student’s test t. A 5%-fixed significance level at $p$-value = 0.05.  
- The linear relationship (goodness of FIT) between the averages of values of each parameter measured by BTS system and the correspondent parameter estimated by POS system was measured by the correlation analysis. The correlation significance was verified by the calculation of Student’s t value.  
- The equivalence between POS system and BTS system was evaluated by the linear simple regression analysis. Regression line methods in which values of the angular coefficient and the intercept are respectively 1 and 0 considered equivalent. Finally, when the correlation was significant, the difference between the measurements made by the 2 methods and the average of these measures was plotted (Bland-Altman method with a
95% confidence interval) in order to obtain an estimation of the closeness between the two systems. All data were subjected first to the Shapiro-Wilk test to verify the Gaussian distribution of data. In the groups where the distribution wasn’t normal, the similar non-parametric paired Student’s t test was used (Wilcoxon test).

**Results**

**A. Intra-operator variability**
The analysis of CV% obtained by each operator showed a good repeatability. For each parameter acquired by FIS-POS System the average of the CV% between 4 subjects was calculated: as shown in Table III; this preliminary analysis underlined greater precision of the measurement of some parameters than others. A CV% <15 is observed in both operators for the acquired data by both FIS and POS.

**B. Inter-operator variability**
First, on the same subject, differences between measures of the 2 operators for each parameter were evaluated (Tab. IV): in all measures made on subjects a p-value>0.05 was observed, which indicates the absence of significant difference between the average measured for each parameter. Only 2 parameters in subject 1 and in subject 4 showed a difference

**Table III. Values of average CV% of all the parameters acquired by the FIS-POS system.**

<table>
<thead>
<tr>
<th>p-value</th>
<th>Subject 1</th>
<th>Subject 2</th>
<th>Subject 3</th>
<th>Subject 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>POS (without heel raise)</td>
<td>0.6329</td>
<td>0.6822</td>
<td>0.9185</td>
<td>0.5744</td>
</tr>
<tr>
<td>POS (with heel raise)</td>
<td>0.3652</td>
<td>0.7172</td>
<td>0.7648</td>
<td>0.5584</td>
</tr>
<tr>
<td>FIS (heel raise height)</td>
<td>0.0967</td>
<td>0.1303</td>
<td>0.3668</td>
<td>0.9496</td>
</tr>
</tbody>
</table>

Figure 7. Parameters acquired from POS and BTS.
of significance between averages of measures taken by the two operators. In order to evaluate the reproducibility, the average of all parameters measured by operator B was compared with the average of all parameters measured by operator A; in this case the data distribution wasn’t normal, so a non-parametric test was taken (Wilcoxon test), which showed a p-value > 0.05 both for FIS system and the POS system (Tab. V).

It can be concluded that the differences between 2 operators were not statistically significant, indicating a good reliability of the measuring system.

C. Inter-method variability

Measures acquired by POS system were compared with that acquired by BTS system, for example linear parameters (distances between landmarks) which build up the right triangles and the trapeziums stated above. In the following graphics are presented regression lines on measures made by the 2 operators with respective angular coefficients (mA, mB) and intercepts (qA, qB). Pearson’s correlation coefficients for each operator (rA, rB) and the Student’s t value (tA, tB) calculated to evaluate the significance of correlation. The evaluation of linear parameters pointed out a highly significant correlation between the two methods: as shown in Figures 8 and 9, the values of Pearson’s correlation coefficient of each operator are very close to the unit, indicating that the correlation between the two methods is very high. The Student’s t values calculated for both operators are higher than the tabulate Student’s t values, indicating that the correlation is statistically significant. The values of angular coefficient and of intercepts of regression line are close respectively to 1 and 0 in all cases. In the Figures 10-13 the Bland-Altman graphics presented the measurement of linear parameters made by the two systems with and without heel raise. The central line represents the average of differences, as noted it is close to zero, indicating a great concordance between the two methods. If the points on the graph are in the confidence interval (IC=average of differences +/- standard deviation), there is a 95% probability to find the true value of the average of differences, the 2 methods provide consistent results. So, linear parameters analysis showed a great concordance between the innovative POS method and the traditional reliable BTS system.

In conclusion, the analysis of inter-method variability showed a high correlation between the two methods, BTS and POS, regarding the acquisition of above parameters.

Discussion

Leg length discrepancy is a relatively common musculoskeletal malalignment related to structural, postural and environmental factors. The discrepancy is an aetiological factor in the development of a variety of overuse injuries as it alters the magnitude and distribution of mechanical stress within the body. LLD has been linked with lower extremity stress fractures, low back pain, hip pain and vertebral disk problems. Literature review was conducted on PubMed without search limitations of language, study design or dates, using functional lower limb discrepancy and lower
Figure 8. Regression lines for measurements without heels (linear parameters).

Figure 9. Regression lines for measurements with heel (linear parameters).

Figure 10. Bland-Altman for measurements with heels (linear parameters, operator A).
Figure 11. Bland-Altman for measurements with heels (linear parameters, operator B).

Figure 12. Bland-Altman for measurements with heels (linear parameters, operator A).

Figure 13. Bland-Altman for measurements with heels (linear parameters, operator B).
limb inequality combined with orthosis, heel lift or pelvic tilt as keywords. It was noted that the majority of literatures main concern was about anatomical type of LLD while some other literatures gave more attention to functional abnormalities associated or isolated from LLD of real type, with recommendations for proper clinical assessment to distinguish between both types for accurate management. The often functional abnormalities associated with LLD are over-pronation of one foot or imbalances within the pelvis itself with a high correlation with injury on the short leg side. There is body of evidence link the foot over-pronation, with other musculoskeletal disorders as mechanical low back pain and knee osteoarthritis through mechanisms based on either mechanical postural changes or alterations in muscular activity in the lumbar and pelvic muscles. In 2015 a cross-sectional survey was conducted to estimate abnormal alignment characteristics among 249 rice farmers. The highest prevalence of lower extremity malalignment was foot pronation (36.14%), while pelvic tilt angle prevalence counted for 30.52%. In spite of the health impact and high prevalence still more research is needed to explore and quantify the effects of assessment/corrective method on treatment of such conditions, especially their effects on lumbo-pelvic muscle function and posture.

For decades customized shoes modifications have been suggested for treatment and recently for prevention of various musculoskeletal diseases. However in published literature customized heel height measured with feet out of load have not been suggested nor tested yet. It is important to take into consideration that using inappropriate foot orthotics can create additional pain instead of alleviating it, while utilizing unilateral heel lift for a functional problem may cause contralateral symptoms instead of treating the condition. It was stated that in LLD, correction of any dysfunction in the pelvis is important because a number of iliosacral and sacroiliac dysfunctions that cause functional changes in leg length would misleadingly appear on standing posture as a short leg. In such cases, the use of unilateral heel lift could aggravate the problem.

In a retrospective descriptive study included 1100 cadets revealed that compliance was poor with the use of a heel lift; this lack of compliance can be blamed for countless poor outcomes in the medical community, moreover it highlights as previously discussed in this section that un-customized heel lift may harm rather than treat the condition. To the best of our knowledge, NPoS system would be the first to be tested as a diagnostic and corrective tool for posture malalignment with measures based on foot assessment out of load plus real time evaluation of correction using personalized heel lift to be applied bilaterally for management of functional lower limb discrepancy. Two studies were found to be based on nearly the same concept as in the present study in terms of quantitative postural parameters utility in assessment of the suitable heel rise required; the anatomic and functional LLD and associated estimation of the pelvic torsion and the use of underfoot wedge corrections to compensate this pelvic tilt was taken into consideration by D’Amico et al. in 2012 who suggested 3D kinematic optoelectronic measurements plus baropodographic system as an useful significant tool to assess postural parameters in scoliotic patients. The posture re-balancing and spine deformities reduction they achieved, pointed out the significant contribution of their approach in assessing the correct under-foot wedge size. However their assessment was done on standing position with weight bearing using serials of wedges of different random sizes applied unilaterally till the optimum rebalancing achieved, while NPoS system application minimized the error of excessive muscle and soft tissue stress by assessing the personalized heel height objectively while feet is off load with muscles relaxed using its FIS component, and to be applied bilaterally and followed by real time control for posture functional re-balancing using its POS component.

Conclusion

Our results suggest a significant validity of NPoS in assessment & real time correction of posture mala- ligmentation of functional lower limb discrepancy, high degree of reproducibility & minimal operator dependence were also obtained. This study can be consid- ered a base for other promising trials to test the possible clinical implications of NPoS as a reliable cost effective postural assessment/corrective tool.

Conflict of interest

The Authors have no conflict of interest.

References