SCIENTIFIC REPORT ON PoDATA SYSTEM

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THE PoDATA SYSTEM

The PoDATA system measures the body weight distribution on feet. Podata is a postural stabilometric bilaminate footboard with a crystal top, and a system with 6 load cells that can be positioned to detect loads on the 1st and 5th metatarsal and heel. It is also used for measuring the center of pressure (COP), the center of foot (COF) and the fluctuations of body’s centre of gravity.

The system in the photograph (GPS400) was used for all the analysis.
The 6 load cells should be positioned to detect loads, according to the first and fifth metatarsal heads and heels. The weight distribution can be reported as percentage of body weight for each analysed point.
AIM OF THE STUDY

The major aims of this study are: 1) to test the reliability of the measures obtained by the PoDATA and 2) to standardize the method of analysis.

1. MEASURE RELIABILITY.

To this purpose both the inter-operator and the intra-operator measure reproducibility were analysed. The main questions were:

- Inter-operator reliability. Do different operators place foot plantar markers in the same places when viewing the same patient?
- Intra-operator reliability. Does the same operator place the markers in the same position when measuring the same patient (unchanged posture) at different times?

2. ANALYSIS STANDARDIZATION.

Several conditions of analysis were tested to define the best procedure in the patient evaluation. Although assessing plantar pressure may seem simple, investigators around the world use a variety of measurement protocols. There is an urgent need for training of health professionals on how to measure it properly and reproducibly.
ANALYZED SAMPLE

Three males and three females were recruited for the analysis. For each subject the percentage of body weight distribution on both feet and on each interest point per foot (1\textsuperscript{st}, 5\textsuperscript{th} metatarsal heads and heel) were analysed. All the percentage values for each subject were simultaneously analysed.

Two experienced operators subsequently measured the same subjects to test inter-operator reliability. For each subject, all the percentage values were matched for the two operators.

Measures were taken twice for each subject by each operator to test the intra-operator reliability. For each subject, all the percentage values were matched for the two measurements.

Several measure conditions were tested twice to define the best procedure in patient analysis standardization. To this purpose, analyses were performed both on room temperature (cold) or pre-heated (warm) platforms. Moreover, for both variables, measures were obtained in absence or presence of 5-min feet conditioning. For instance, patients were asked to remove shoes and 1] immediately climb on the platform (no conditioning) or; 2] wait 5 minutes on the floor (5-min conditioning on hard surface) or, 3] wait 5 minutes on a 3cm thick foam mat (5-min conditioning on soft surface).

For each subject, all the percentage values were matched for the indicated conditions of analysis.

All the measures were performed by the same PODATA system and PC and statistically analysed.
STATISTICS

The Measurement of Linear Correlation and Regression

Correlation and regression are two sides of the same statistical coin. When you measure the linear correlation of two variables (X and Y), what you are in effect doing is laying out a straight line that best fits the average "together-movement" of these two variables.

The Pearson product-moment correlation coefficient \( R \) – which ranges in value from \( R=+1.0 \) for a perfect positive correlation to \( R=0.0 \) for a complete absence of correlation – was analysed for all the data. Values falling between \( R=0.0 \) and \( R=+1.0 \) represent varying degrees of positive correlation.

The coefficient of determination \( (R^2) \) values ranging from \( R^2=+1.0 \) for a perfect correlation down to \( R^2=0.0 \) for a complete absence of correlation. It provides an equal interval and ratio scale measure of the strength of the correlation.

Both of them together were calculated to obtain the whole works.

The line of regression helps to visualize the relationship between the two variables and can also be very useful as a basis for making rational predictions. The location and orientation of the regression line are defined by two constants. These are the intercept, point at which the line crosses the Y axis, and the slope, the rate at which the line angles upward or downward along the X axis.

Interpretation of Correlation and Regression

For example, the correlation \( R^2=1.0 \) is 100% as strong as it possibly could be, whereas the one \( R^2=0.50 \) is only 50% as strong as it possibly could be.

The essential meaning of "strength of correlation" in this context is that such-and-such percentage of the variability of Y is associated with (tied to, linked with, coupled with) variability in X, and vice versa. Thus, for 100% of the variability in Y is coupled with variability in X means the coincidence of X and Y values.

A higher slope value indicates a steeper incline. The larger the absolute value of a slope, the steeper the line. A horizontal line has slope 0, a 45° rising line has a slope of +1, and a vertical line's slope is undefined meaning it has "no slope."
On the basis of these concepts, two coincident variable (Xi and Yi) are defined by the following statistical data:

- **N**: 8
- **y = x**
- **R**: 1.0
- **R²**: 1.0
- **Slope**: 1.0
- **Y intercept**: 0
- **Two-tailed P**: < 0.0001

![Graph showing a linear regression with y = x, R² = 1](image-url)
STUDY OF INTER-OPERATOR MEASUREMENT RELIABILITY

This study gives the reliability of measurements made by two different operators using the same PODATA system.

METHODS

Two different expert users (operators #1 and #2) subsequently and independently analysed the same three subjects.

At the end of the first measurement, each subject was asked to wear shoes and wait (5-min) for the next analysis by the second operator.

Each operator followed the same procedure: subjects were asked to remove shoes and to climb on the platform (in the absence of feet conditioning)

All the measures were performed at room temperature platform.

For each experimental condition, values from each subject were compared.
INTER-OPERATOR RESULTS

N: 22

\[ y = 1.0311x - 1.1682 \]

R: 0.978

R^2: 0.957

Slope: 1.041

Y intercept: -1.585

Two-tailed P: < 0.0001

0.95 Confidence interval for rho

Lower limit: 0.948

Upper limit: 0.991

0.95 Confidence Interval for the Slope

Lower limit: 0.938

Upper limit: 1.144
STUDY OF INTRA-OPERATOR MEASUREMENT RELIABILITY

This study gives the reliability of repetitive measurements made by the same operator on the same subject.

METHODS

Six subjects were measured twice by the same operator. Measures taken under the same conditions were compared.

Subsequently, the platform temperature was analysed for its incidence on measure reliability.

For each experimental condition, values from each subject were compared.
INTRA-OPERATOR RESULTS

RESULTS OF ANALYSIS OF TWO REPEATED MEASURES

N: 144
y = 0.984x + 0.6001
R: 0.928
R²: 0.861
Slope: 0.988
Y intercept: 0.409
Two-tailed P: < 0.0001

0.95 Confidence interval for rho
Lower limit: 0.901
Upper limit: 0.947

0.95 Confidence Interval for the Slope
Lower limit: 0.922
Upper limit: 1.054
RESULTS OF ANALYSIS OF TWO REPEATED MEASURES ON COLD PLATFORM

N: 72
y = 0.945x + 2.0639
R: 0.947
R²: 0.897
Slope: 0.948
Y intercept: 1.910
Two-tailed P: < 0.0001

0.95 Confidence interval for rho
Lower limit: 0.917
Upper limit: 0.966

0.95 Confidence Interval for the Slope
Lower limit: 0.871
Upper limit: 1.025
RESULTS OF ANALYSIS OF TWO REPEATED MEASURES ON WARM PLATFORM

N: 72
y = 1.0363x – 1.3597
R: 0.910
R²: 0.827
Slope: 1.042
Y intercept: -1.619
Two-tailed P: < 0.0001

0.95 Confidence interval for rho
Lower limit: 0.859
Upper limit: 0.942

0.95 Confidence Interval for the Slope
Lower limit: 0.928
Upper limit: 1.155
WARM PLATFORM

MEASURE #2

MEASURE #1
STUDY OF ANALYSIS STANDARDIZATION

This part of the study is focused on the definition of the best procedure in patient evaluation, to standardize the method of analysis.

METHODS

Six subjects were analysed twice under several conditions of measurement, as summarized below.

- **Platform temperature.** Analyses were performed both on room temperature (cold) or pre-heated (warm) platform.
- **Feet conditioning.** For both variables (cold / warm platform), measures were obtained in absence or presence of 5-min feet conditioning.
- **Conditioning surface.** In the case of 5-min feet conditioning (floor), this was performed either on a hard or on a soft surface (3cm thickness foam mat).

For each experimental condition, values from each subject were compared.
RESULTS OF ANALYSIS ON COLD AND WARM PLATFORM

RESULTS OF ANALYSIS ON COLD AND WARM PLATFORM INDEPENDENTLY BY PATIENT CONDITIONING

N: 168

\[ y = 0.8893x + 4.152 \]

R: 0.945

R^2: 0.894

Slope: 0.907

Y intercept: 3.518

Two-tailed P: < 0.0001

0.95 Confidence interval for rho

Lower limit: 0.927

Upper limit: 0.959

0.95 Confidence Interval for the Slope

Lower limit: 0.859

Upper limit: 0.955
RESULTS OF ANALYSIS ON COLD AND WARM PLATFORM WITHOUT PATIENT CONDITIONING

\[ y = 0.9572x + 1.604 \]

- \( R: 0.952 \)
- \( R^2: 0.907 \)
- \textbf{Slope}: 0.952
- \textbf{Y intercept}: 1.854
- \textbf{Two-tailed P}: < 0.0001

\textit{0.95 Confidence interval for rho}

- \textbf{Lower limit}: 0.920
- \textbf{Upper limit}: 0.971

\textit{0.95 Confidence Interval for the Slope}

- \textbf{Lower limit}: 0.869
- \textbf{Upper limit}: 1.036
RESULTS OF ANALYSIS ON COLD AND WARM PLATFORM AFTER 5-MIN PATIENT CONDITIONING ON HARD SURFACE

N: 56
y = 0.8891x + 4.1571
R: 0.933
R²: 0.870
Slope: 0.889
Y intercept: 4.153
Two-tailed P: < 0.0001

0.95 Confidence interval for rho
Lower limit: 0.888
Upper limit: 0.960

0.95 Confidence Interval for the Slope
Lower limit: 0.795
Upper limit: 0.983
5 min CONDITIONING ON HARD SURFACE

WARM PLATFORM

COLD PLATFORM
RESULTS OF ANALYSIS ON COLD AND WARM PLATFORM AFTER 5-MIN PATIENT CONDITIONING ON SOFT SURFACE

N: 56
y = 0.9572x + 1.604
R: 0.952
R²: 0.907
Slope: 0.882
Y intercept: 4.478
Two-tailed P: < 0.0001

0.95 Confidence interval for rho
Lower limit: 0.920
Upper limit: 0.971

0.95 Confidence Interval for the Slope
Lower limit: 0.805
Upper limit: 0.960
5 min CONDITIONING ON SOFT SURFACE

WARM PLATFORM

COLD PLATFORM
RESULTS OF ANALYSIS AFTER NO CONDITIONING OR 5-MIN PATIENT CONDITIONING ON HARD SURFACE INDEPENDENTLY BY THE PLATFORM TEMPERATURE

N: 112
\[ y = 0.9397x + 2.2607 \]
R: 0.931
R²: 0.867
Slope: 0.926
Y intercept: 2.764
Two-tailed P: < 0.0001

0.95 Confidence interval for rho
Lower limit: 0.901
Upper limit: 0.951

0.95 Confidence Interval for the Slope
Lower limit: 0.857
Upper limit: 0.995
RESULTS OF ANALYSIS ON COLD PLATFORM AFTER NO CONDITIONING OR 5-MIN CONDITIONING ON HARD SURFACE

N: 56
y = 0.9321x + 2.5469
R: 0.947
R²: 0.897
Slope: 0.964
Y intercept: 1.347
Two-tailed P: < 0.0001

0.95 Confidence interval for rho
Lower limit: 0.912
Upper limit: 0.968

0.95 Confidence Interval for the Slope
Lower limit: 0.875
Upper limit: 1.054
RESULTS OF ANALYSIS ON WARM PLATFORM AFTER NO CONDITIONING OR 5-MIN CONDITIONING ON HARD SURFACE

N: 56
y = 0.9481x + 1.9461
R: 0.914
R²: 0.836
Slope: 0.887
Y intercept: 4.183
Two-tailed P: < 0.0001

0.95 Confidence interval for rho
Lower limit: 0.858
Upper limit: 0.948

0.95 Confidence Interval for the Slope
Lower limit: 0.780
Upper limit: 0.995
ABSENCE OF CONDITIONING

WARM PLATFORM

5 min CONDITIONING ON HARD SURFACE
RESULTS OF ANALYSIS AFTER NO CONDITIONING OR 5-MIN CONDITIONING ON SOFT SURFACE

N: 112
y = 0.9659x + 1.2709
R: 0.954
R²: 0.910
Slope: 0.943
Y intercept: 2.231
Two-tailed P: < 0.0001

0.95 Confidence interval for rho
Lower limit: 0.934
Upper limit: 0.968

0.95 Confidence Interval for the Slope
Lower limit: 0.886
Upper limit: 0.999
CUMULATIVE DATA

ABSENCE OF CONDITIONING

5 min CONDITIONING ON SOFT SURFACE
RESULTS OF ANALYSIS ON COLD PLATFORM AFTER NO CONDITIONING OR 5-MIN CONDITIONING ON SOFT SURFACE

N: 56
\[ y = 0.9234x + 2.8736 \]
R: 0.947
R²: 0.898
Slope: 0.971
Y intercept: 1.160
Two-tailed P: < 0.0001

0.95 Confidence interval for rho
Lower limit: 0.912
Upper limit: 0.968

0.95 Confidence Interval for the Slope
Lower limit: 0.882
Upper limit: 1.061
RESULTS OF ANALYSIS ON WARM PLATFORM AFTER NO CONDITIONING OR 5-MIN CONDITIONING ON SOFT SURFACE

N: 56

\[ y = 1.0154x - 0.5946 \]

R: 0.962

R\(^2\): 0.926

Slope: 0.914

Y intercept: 3.302

Two-tailed P: < 0.0001

0.95 Confidence interval for rho

Lower limit: 0.937

Upper limit: 0.977

0.95 Confidence Interval for the Slope

Lower limit: 0.843

Upper limit: 0.985
RESULTS OF ANALYSIS AFTER 5-MIN CONDITIONING ON SOFT OR HARD SURFACES

N: 112

\[ y = 0.9652x + 1.2991 \]

R: 0.961

R\(^2\): 0.924

Slope: 0.967

Y intercept: 1.130

Two-tailed P: < 0.0001

0.95 Confidence interval for rho

Lower limit: 0.944

Upper limit: 0.973

0.95 Confidence Interval for the Slope

Lower limit: 0.915

Upper limit: 1.020
RESULTS OF ANALYSIS ON COLD PLATFORM AFTER 5-MIN CONDITIONING ON SOFT OR HARD SURFACES

N: 56
\[ y = 0.9526x + 1.7757 \]
R: 0.960
R^2: 0.922
Slope: 0.954
Y intercept: 1.67
Two-tailed P: < 0.0001

0.95 Confidence interval for rho
Lower limit: 0.933
Upper limit: 0.976

0.95 Confidence Interval for the Slope
Lower limit: 0.878
Upper limit: 1.029
COLD PLATFORM

5 min CONDITIONING ON SOFT SURFACE vs. 5 min CONDITIONING ON HARD SURFACE
RESULTS OF ANALYSIS ON WARM PLATFORM AFTER 5-MIN CONDITIONING ON SOFT OR HARD SURFACES

N: 56
y = 0.9797x + 0.7452
R: 0.962
R²: 0.926
Slope: 0.983
Y intercept: 0.502
Two-tailed P: < 0.0001

0.95 Confidence interval for rho
Lower limit: 0.937
Upper limit: 0.977

0.95 Confidence Interval for the Slope
Lower limit: 0.907
Upper limit: 1.059
CONCLUSIONS

Inter and intra-operator reliability

The inter- and intra-operator variability in measuring foot plantar pressure was assessed. Repeated measures analysis of linear correlation and regression was used to assess the significance of the inter- and intra-operator concordance.

**Inter-operator.** The measures obtained by the two operators ($R^2=0.96$ slope=1.04; see Pag. 10) show a high degree of coincidence, suggesting that homogeneously well trained operators are interchangeable in the measurement of same patient. The protocol followed must be the same.

**Intra-operator.** The analysis of repeated measures obtained by the same operator (Pag. 12) shows a $R^2$ value ranging from 0.83 to 0.90 and a slope ranging from 0.95 to 1.04. This means that a high degree of agreement can be achieved when the same operator measures the same patient (with unchanged postural scheme) different times. The protocol followed must be the same.

Analysis standardization

Several conditions potentially affecting foot plantar pressure were taken in account. Repeated measures analysis of linear correlation and regression were used to assess the best measurement condition.

**Platform temperature.** Analyses were performed both on room temperature (cold) or pre-heated (warm) platform (Pag 20). The $R^2$ value ranging from 0.86 to 0.90 and a slope ranging from 0.88 to 0.95. The data show that platform temperature virtually does not interfere with the measurement.
Feet conditioning. Measures obtained in absence or presence of 5-min feet conditioning (Pag. 28) show $R^2$ values ranging from 0.84 to 0.93 and a slope ranging from 0.89 to 0.97. The data show that feet preconditioning virtually does not interfere with measures. This implies that no additional time is required for a correct measurement.

Conditioning surface. In case of 5-min feet conditioning, it was performed on a hard (floor) or on a soft surface (3cm thick foam mat) (Pag. 40). The $R^2$ value ranged from 0.92 to 0.93 and slope ranged from 0.95 to 0.98. The data show a substantial coincidence of values obtained in the two conditions.

In conclusion, PoDATA measures result both reproducible and reliable. Platform does not need temperature control and patients can be analysed immediately after their arrival.

However, all the measurements reported in this study were performed with a strict protocol, to which both the expert operators were tight.
MEASUREMENT PROTOCOL

Patient preparation

1. The patient is asked to:
   - remove clothes, except her/his underwear, shoes and socks\(^a\);
   - sit on a cot showing the sole of the feet.
2. The operator marks the 1\(^{st}\) and 5\(^{th}\) metatarsal heads and the heels, after finding them by direct palpation.
3. The patient is asked to:
   - climb on the PoDATA platform\(^b\);
   - perform two steps in place;
   - stop feet and to not move them until the end of the exam;
   - look forward (to the horizon);
   - arms relaxed at her/his sides

Analysis

The operator acts as follow:
- controls the patient posture on the PoDATA (as described above);
- takes the picture of the feet soles;
- recognizes the markers on the soles;
- puts the 6 load cells in correspondence of the markers;
- starts the examination;
- constantly controls patient posture\(^c\)

\(^a\)Note. It is important to see patients' ankles and body posture, during the examination. Clothes, in particular trousers, might interfere.

\(^b\)Note. In case the patients have to wait before the analysis, we suggest to ask them to stay on a foam mat.

\(^c\)Note. Patients frequently do not understand the importance to not move their feet or body. For this reason it is really important to constantly observe patient's movements.