

SUPPLEMENTARY MATERIAL

- Appendix 1. Kappa coefficient & Inter-observer agreement in Tinel sign .

Surgeon_A	Surgeon_B		Total
	Negative	Positive	
Negative	82	10	92
Positive	1	7	8
Total	83	17	100

A very simple measure of the agreement will be the observer agreement ($p_o = n \text{ agreements} / \text{total } n \text{ of observations}$). The tables in this appendix demonstrate an analysis of a hypothetical data set of the agreement in the assessment of Tinel sign (present vs absent), showing a global agreement of $p_o = (82+7)/100 = 89\%$.

	Estimate	95% Confidence Interval			
Specific Agreement (+)	56.0%	37.1%	to	73.3%	(Wilson)
Specific Agreement (-)	93.7%	89.1%	to	96.5%	(Wilson)
Global Agreement (+)	89.0%	81.4%	to	93.7%	(Wilson)
kappa minimum	-0.0582				
kappa maximum	0.7826				

But, is a global agreement of 89% interesting when we do not have agreement in the positive assessment (present Tinel sign)?, Cichetti and Feinstein (1990) recommended the assessment of positive agreement and negative agreement. Positive agreement is the conditional probability of a positive assessment by observer A and observer B (specific positive agreement of $p_{o+} = 2*7/(100+7-82) = 56\%$ means that the probability that observer A classified the Tinel sign as positive when observer B classified it as positive too) (see Tables above)). Negative agreement is the conditional probability of a negative assessment by both observers (specific negative agreement of $p_{o-} = 2*82/(100+82-7) = 93.7\%$). Another limitation of the global agreement (p_o) is that it does not take into account the agreement that can obtained only by chance, called expected agreement (p_e). The maximum true agreement or potential agreement will be equal to $1-p_e$.

kappa	Standard Error		p value	95% Asymptotic Confidence Interval
	SE0	SE1		
0.5063	0.0915	0.1246	0.0000	0.2622 to 0.7504

The Kappa coefficient is one of the most used indexes of agreement which solved that problem because it excluded the expected agreements obtained by chance (Fleiss et

al., 2003). It is calculated by dividing the true agreement by the potential agreement ($Kappa = p_0 - p_e / 1 - p_e$).

Observed Disagreement		Bias Index	Bias adjusted kappa BAK
X-Y+	X+Y-		
1.00%	10.0%	-9.00%	0.4971
Observed Agreement		Prevalence Index	Prev. & Bias adjusted kappa PABAK
(+)	(-)		
12.5%	87.5%	-75.0%	0.7800

Other important aspect in the interpretation of the Kappa value is the effect of bias and prevalence. Bias in agreement analysis is the tendency to misclassify variables in a consistent way that tips the scale in one particular direction. In table 1, we can observe how hand surgeon A classified Tinel sign as positive in 10% of the individuals when hand surgeon B classified it as negative. In addition, hand surgeon B classified Tinel sign as positive in 1% of the individuals while hand surgeon A classified it as negative. There was an asymmetric observed disagreement pair. Byrt et al. (1993) defined the Bias Index (BI) as the differences of the proportions of positive assessments between observer A and observer B. The bias-adjusted Kappa (BAK) is the kappa coefficient adjusted for the bias, which is obtained by replacing the disagreement pair by its mean. Prevalence Index is defined as the difference between the proportion of positive and negative assessments by observer A and observer B. The prevalence-adjusted bias-adjusted Kappa (PABAK) is the Kappa coefficient adjusted for bias and prevalence .

- **Appendix 2. Agreement for a categorical variable.**

When the categorical criterion presents more than 2 categories ($c > 2$) with an order, the agreement should be analysed by the weighted kappa coefficient . However, if the categorical response variable is nominal the results of agreement should be based on the unweighted kappa coefficient with a coefficient for each category compared with the rest . An important, and unsolved, problem is that related to the use of the weighted kappa and the number of categories in the response variable.

The following table shows the test - re test reliability analysis in the assessment of Absent Palmaris Longus (PL) in general population. The response variable (Absence of Palmaris Longus) presented 3 categories: No absent PL, Unilateral absent PL, Bilateral absent PL. The results of agreement analysis will be different if the researcher considers the categorical variable nominal or ordinal.

Observat~1	Observation2			Total
	Bilateral	Unilateral	No absent	
Bilateral	5	0	1	6
Unilateral	0	4	0	4
No absent	1	3	10	14
Total	6	7	11	24

The same observer assessed the palmaris longus (PL) as present vs absent on two occasions, 1 month apart, in a sample of 24 individuals.

A. Nominal categorical response variable (without order)

Weight	Observed Agreement	Kappa	Standard Error		p value	95% Asymptotic Conf. Interval
			SE0	SE1		
UnWeighted	79.2%	0.6648	0.1430	0.1322	0.0000	0.4058 to 0.9238
Categories:						
Bilateral-R	91.7%	0.7778	0.2041	0.1494	0.0001	0.4849 to 1.0707*
Unilateral-R	87.5%	0.6538	0.1915	0.1754	0.0006	0.3101 to 0.9976
No absent-R	79.2%	0.5890	0.1978	0.1586	0.0029	0.2781 to 0.9000

(A) If the response variable is considered as nominal (bilateral absent, unilateral absent or present in both hands) the analysis is done with the unweighted kappa, comparing each class of the response variable with the rest.

B. Ordered categorical response variable

Weight	Observed Agreement	Kappa	Standard Error		p value	95% Asymptotic Conf. Interval
			SE0	SE1		
UnWeighted	79.2%	0.6648	0.1430	0.1322	0.0000	0.4058 to 0.9238
Lineal	85.4%	0.6693	0.1662	0.1424	0.0001	0.3902 to 0.9484
Quadratic	88.5%	0.6733	0.2017	0.1635	0.0008	0.3528 to 0.9937

(B) If the response variable is considered as categorical, in this case with a metric 0,1,2 (0=Bilateral absent, 1=Unilateral absent, 2= Present in both hands) the appropriate agreement coefficient is the weighted kappa.

- **Appendix 3. Intraclass Correlation Coefficient.**

The base of formulation of the ICC was introduced by Fisher (1921) from a special definition of the Pearson correlation coefficient in data with equal mean and variance (Domenech 2017). Actually, the ICC that we use for analysing agreement is based on the analysis of the variance (ANOVA) with repeated measures.

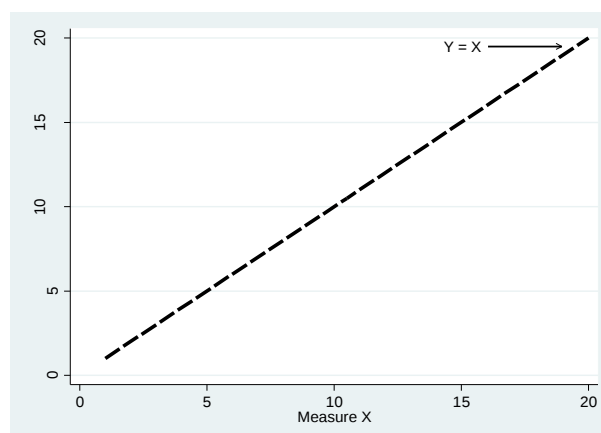
When we face “n” subjects and “K” observers the ICC is based on a two-way ANOVA with two models; random-effect and mixed-effect models. If we have assumed that the n subjects and the K observers came from a random sample of the population, we should use a random-effect model of ICC. Otherwise, if we have considered that the k observers constitute a total representation of the population, we should use a mixed-effect model.

The interpretation of the results differs depending on the model. The ICC obtained by a random-effect model can be generalized to the total population of observers, while the results coming from a mixed-effect model cannot be generalized and it is expected that they will change with a different group of observers. A different situation happens when the assessment has been done by one observer or it is impossible to distinguish the observers, in that case we have to use the “ICC one factor” based on one-way ANOVA, which always presents a random-effect model because the n individuals is a random sample of the population. In summary, for intra-observer reliability (n subjects and one observer) the ICC agreement analysis should be a “one-way, random-effect” model and for inter-observer reliability (n subjects and K observers) could be a “two-way, random-effect” model or “two-way, mixed-effect” model. (Vaz et al. 2013).

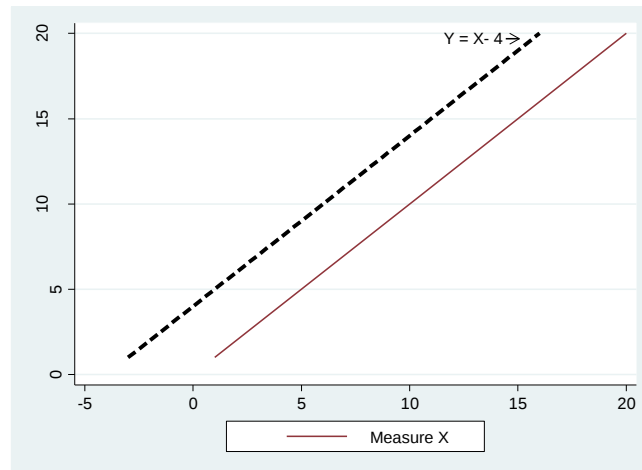
One other important aspect of the ICC is that any model (one-way random-effect, two-way random-effect, and two-way mixed-effect) could have two different systems of agreement assessment; consistency and absolute agreement. The following charts help to understand the close concepts of Pearson correlation, ICC consistency agreement, and ICC absolute agreement. Observe the changes in ICC, ICCA and r related to three different bias situations.. In A the assessments by X and Y are similar and the ICC, ICCA and Pearson correlation (r) coefficients are similar too. In B it is shown a bias in which one a constant disagreement of -4 between observer X and observer Y. Observer Y assessed, in a systematic way, minus 4 points compared with observer X. The r and ICC did not detect that bias, only the ICCA showed a lower agreement coefficient of 0.814. In C, it is shown a proportional disagreement in which observer Y assessed in systematic way dividing by 3 the observations done by observer X. In that proportional bias, the r coefficient was unable to detect it, while both the ICC and ICCA show lower coefficients (0.6 and 0.268 respectively). Chart D shows a constant and proportional disagreement which was detected only by the ICCA (0.147). A constant and proportional disagreement is detected only by ICCA. (based on Domenech 2017). Consequently, for test retest reliability, the recommendation is to use the ICC_{2,1} that defines a two-way random-effect model with absolute agreement (Vaz et al. 2013; Rosales et al., 2017).

A**Total Agreement ($Y=X$)**Consistency: $ICC_C = 1$ Absolute: $ICC_A = 1$ Pearson correlation $r = 1$

Id	X	Y
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9
10	10	10

**B****Constant Disagreement ($Y=X-4$)**Consistency: $ICC_C = 1$ Absolute: $ICC_A = 0.814$ Pearson correlation $r = 1$

Id	X	Y
1	1	-3
2	2	-2
3	3	-1
4	4	0
5	5	1
6	6	2
7	7	3
8	8	4
9	9	5
10	10	6



C

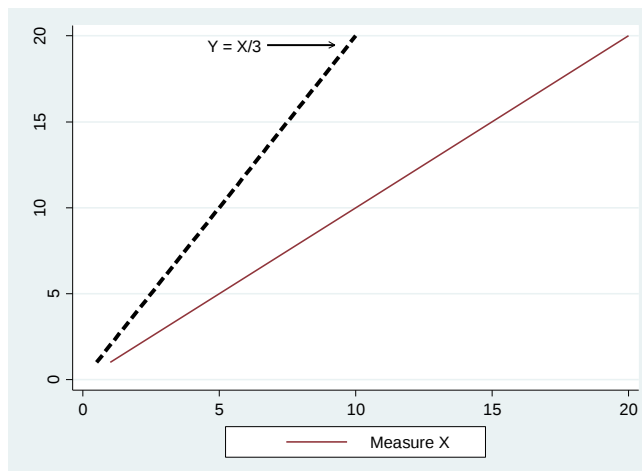
**Proportional Disagreement
($Y = X/3$)**

Consistency: $ICC_C = 0.600$

Absolute: $ICC_A = 0.268$

Pearson correlation $r = 1$

Id	X	Y
1	1	.33
2	2	.67
3	3	1
4	4	1.3
5	5	1.7
6	6	2
7	7	2.3
8	8	2.7
9	9	3
10	10	3.3



D

Proportional & Constant

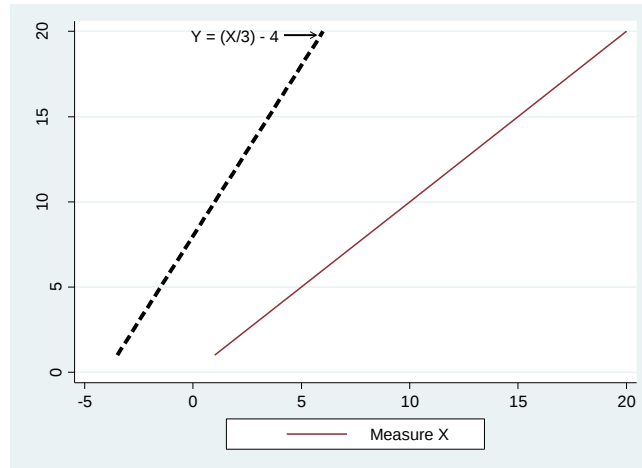
Disagreement ($Y = (X/3) - 4$)

Consistency: $ICC_C = 0.600$

Absolute: $ICC_A = 0.147$

Pearson correlation $r = 1$

Id	X	Y
1	1	-3.7
2	2	-3.3
3	3	-3
4	4	-2.7
5	5	-2.3
6	6	-2
7	7	-1.7
8	8	-1.3
9	9	-1
10	10	-.67



- **Appendix 4. Bland-Altman Limits of Agreement (LoA) for studying agreement between two methods of assessment of a quantitative criterion.**

The results of comparing two methods (X and Y) of measuring the preoperative pulp-to-pulp pinch strength (Kg) in patients with thumb carpometacarpal (CMC) osteoarthritis.

The Bland-Altman limits of agreement (LoA) calculate the difference between both measures for each subject ($d_i = Y_i - X_i$) and it is faced with the mean ($m_i = (X_i + Y_i)/2$) of both measures for each individual. If we assume the normality distribution of the differences, it is expected that 95% of the differences should be between the limits of the interval. In fig. 1 we observe how most of the differences are localized between the LoA.

The following tables present the descriptive statistics of Bland-Altman analysis with a listwise strategy which means that the missing values are not included in the analysis.

Bland-Altman: Descriptive Statistics (listwise)

Variable	Valid	Miss	Obs	Mean	Std. Dev.	[95% Conf. Interval]	
Y: P_Pnew	93	0	93	3.030466	.7985896	2.865998	3.194934
X: P_Pstand	93	0	93	3.065689	.7604395	2.909078	3.2223

Valid number of cases (listwise): 93

With a sample of $n = 93$ subjects and LoA with a 95% CI, it is expected that no more than 4.65 observations ($0.05 * 93 = 4.65$ or 2.33 over the limit and 2.33 under the limit) will be outside of the LoA. The following table shows that 3 cases were over and 3 cases were under the LoA. Observe that there was no bias ($d_o = -0.035$) with a 95% CI (-0.1086 to 0.0381637) which was not statistically significant because the 95% CI includes the null hypothesis ($H_0; d_o = 0$).

Bland-Altman: Absolute values of Bias & Limits of Agreement (LoA)

Parameter		Estimate	Std. Dev.	Std. Err.	[95% Conf. Interval]	
Diff. (Y-X):	Bias	-.0352232	.3563379	.0369505	-.1086101	.0381637
	Lower LoA	-.7336326		.0640002	-.8607424	-.6065227
	Upper LoA	.6631862		.0640002	.5360763	.790296

Cases over limit = 3 (3.23%)

Cases under limit = 3 (3.23%)

Spearman correlation between (Y-X) and (X+Y)/2: $r = 0.0964$ ($p = 0.3579$)

Lin's Concordance Correlation coeff. of Absolute Agreement = 0.8947

Besides, some statistics software as in the following table gives the Lin concordance absolute agreement (Lin 1989;1992) which was 0.894 (good to excellent agreement) and the Shapiro-Wilk test for normality ($W=0.981$, $p=0.195$) indicating that the differences (d_0) followed a normal distribution with information about skewness and kurtosis of the distribution of the differences. The Bland-Altman LoA can be applied only if the differences followed a normal distribution.

Tests of Normality (Y-X)	Statistic	p-value
Shapiro-Wilk	$W = 0.9810$	0.1952
Skewness	$Sk = -0.0437$	0.8542
Kurtosis-3	$Ku = 1.2039$	0.0364
Skewness & Kurtosis	$Chi2 = 4.4945$	0.1057

Bland-Altman limits of agreement (LoA) method calculates the difference between both measures for each subject ($d_i = Y_i - X_i$) and it is faced with the mean ($m_i = (X_i + Y_i)/2$) of both measures for each individual. If we assume the normality distribution of the differences, it is expected that the 95% of the differences should be between the limits of the interval. At the end, Stata supplies the normality analysis with the Shapiro-Wilk test (Null hypothesis $H_0 =$ There is no difference between the sample and a normal distributed population).

- **Appendix 5. Comparison of two methods for measuring pulp-to-pulp pinch strength in patients with thumb CMC osteoarthritis by Passing Bablok regression line of agreement**

The Passing and Bablok analysis (Passing and Bablok 1984; 1985; 1988), is a non-parametric estimation of the orthogonal regression line between the two methods. The lineal equation will be $Y = A + BX + \epsilon$, in which A is the constant difference between the two methods, B is the proportional difference, and ϵ is a random variable with a mean equal to zero which represents the random non-systematic error between the methods. When $A = 0$ and $B = 1$ means that both methods presented the same error and they are comparable. The following table shows an A value -0.1428571 (95% CI: -0.5151515 to 0.0958333), not significant

because the 95% CI includes the $H_0 = 0$. The B coefficient was : 1.047619 (95% CI: 0.9625 to 1.166667), not significant because it included the $H_0 = 1$ (in a rate or proportion $H_0 = 1$ when the numerator is similar to denominator). Consequently, based on the Passing and Bablok analysis we can conclude that the two methods presented no constant and proportional differences and they are comparable. Observe the same Lin's concordance coefficient of agreement (0.8947) than that one obtained in the Bland-Altman analysis.

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. agree P_Pnew P_Pstand , pb
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AGREEMENT: PASSING-BABLOK METHOD

Passing-Bablok: Descriptive Statistics (listwise)

Variable	Valid	Miss	Obs	Median	Mean	Minimum	Maximum	Std. Dev.
Y: P_Pnew	93	0	93	3	3.030466	1.333333	5	.7985896
X: P_Pstand	93	0	93	3.090909	3.065689	1.272727	4.818182	.7604395
Y-X	93	0	93	-.030303	-.0352232	-1.075758	1.151515	.3563379
100*(Y-X)/X	93	0	93	-.9009%	-.8411%	-31.9%	36.2%	11.8%

Valid number of cases (listwise): 93

Passing-Bablok: Regression Line ($Y = A + B \cdot X$)

A =	-.1428571	(95% CI: -.5151515 to .0958333)
B =	1.047619	(95% CI: .9625 to 1.166667)

Linearity Test (CUSUM Test for deviation from linearity): $p > 0.20$

Lin's Concordance Correlation coeff. of Absolute Agreement = 0.8947

- **Appendix 6. Internal consistency & Cronbach alpha.**

The Cronbach alpha can be derived by using split-half reliability coefficients, calculated by randomly dividing items into two subscales and then correlating the item responses of each subscale with each other. The alpha coefficient represents the average of all possible split-half correlations and typically varies between 0 and 1.

- **Appendix 7. Structural Validity**

The structural validity analysis under CTT is done by Factor Analysis (FA), which is a collection of statistical techniques that try to identify if there are clusters of items that go together. Ideally, a scale measures just one concept, but some concepts may be multidimensional (e.g., PRO instruments that measure health may have one dimension for physical health and a second for mental health). We will expect that those dimensions should be correlated but that correlation should be small enough that we can identify them as two different dimensions of health. Analysing the scale with FA permits us to recognise the set of items that represent each dimension. We may find a first group of items that are strongly correlated and with a pattern of correlation that is consistent, and a second different set of items with a high correlation among them representing the other health dimension, and both sets of items should have a small or moderate correlation with each other.

An alternative method for analysing structural validity is IRT. In CTT, scoring of the measures is usually done by summing or averaging item scores on a set of items, each of which has equal weight. In that way the PRO instrument yields the scores with an error measurement. IRT was developed to overcome the problems of CTT, namely that the item statistics are very dependent on the sample of respondents, the interpretation of respondent characteristics depends on the questionnaire used, and the assumption that errors of measurement are equal for all persons. Finally, CTT cannot make prediction about results for a respondent or a sample, on an item using only their ability scores (Embreston 1966; Embreston & Reise., 2000). ITR enables to predict a person's scores based on his/her abilities or latent traits and to establish a relationship between a person's item performance and the set of traits underlying item performance. Consequently, once the data fit an IRT model, the same items may be used in different samples and they will keep their statistical properties (for instance, difficulty and discrimination) independently of the sample's ability to respond to the items (Hamblenton 1996). The use of ITR is not common in PRO assessment in hand surgery but has been used to assess the psychometric properties of the DASH in Dupuytren disease (Forget et al. , 2014) and the CTS-6 in CTS (Lyren et al 2012).

- **Appendix 8. References (complete list)**

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