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System to measure the range of motion of the joints of the human hand

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ABSTRACT

Today, the manual goniometer is a common tool used in clinical practice to measure the range of motion (ROM) of joints in the hand. This device is not only tedious and highly time-consuming to use, but its accuracy mainly depends on the experience of the examiner. The majority of electronic goniometers currently available on the market exhibit these same limitations. This document presents the physical design and attributes of a system known as the MULTIELGON, which can be used automatically to obtain multiple measurements of the angles of the hand's small finger joints simultaneously using a novel angle-to-voltage transducer. The reproducibility and repeatability of the transducer were evaluated; low dispersion and high homogeneity were demonstrated. Correlation and Bland-Altman analyses were used to compare the accuracy of the novel transducer (A) and traditional manual goniometer (B); the correlation coefficient was 0.9995. The Bland-Altman analysis determined the limits of agreement (1.4° to 1.7°) with a 95% confidence interval for any variation between the instruments (A and B), which gave readings differing by less than 3.1°. Differences were sufficiently small to propose that the manual goniometer can be replaced by the transducer; moreover A is best to evaluate the hand's small finger joints than B. The system is comprised of the device, the interface and the MULTIELGON GUI. The device consists of 14 angle-to-voltage transducers that can be attached to joints in the hand using a PVC clamp and an elastic glove. The MULTIELGON can be utilized to evaluate patients, as well as record and manage ROM data for surgical and rehabilitation decisions.

Key words. Bland-Altman. Goniometer. Human Kinematics. ROM.

Sistema para medir el rango de movimiento de las articulaciones de la mano

RESUMEN

Hoy en día el goniómetro manual es la herramienta de medición más utilizada en la práctica clínica para medir el rango de movimiento (ROM) de las articulaciones. El uso de este dispositivo no sólo es tedioso sino que la exactitud de las medidas depende de la experiencia del examinador, quien emplea mucho tiempo para realizar la exploración. La mayoría de los goniómetros electrónicos disponibles en el mercado presentan las mismas limitaciones. En este trabajo se presenta tanto el diseño como la evaluación del sistema conocido como MULTIELGON, el cual permite obtener de manera simultánea y automática mediciones múltiples de los ángulos de las pequeñas articulaciones de la mano usando un transductor ángulo-voltaje expresamente diseñado para este propósito. A partir de análisis estadístico se evaluó la reproducibilidad y la repetitividad del transductor; demostrando baja dispersión y alta homogeneidad en las mediciones. Los análisis de correlación y de Bland-Altman se usaron para comparar la exactitud de este nuevo transductor (A) con respecto al tradicional goniómetro manual (B); el coeficiente de correlación fue de 0.9995. A través del análisis Bland-Altman se determinaron los límites de concordancia (1.4° a 1.7°) entre los instrumentos A y B para un intervalo de confianza del 95%, dando lectura con diferencia menores a 3.1°. Estas diferencias fueron lo suficientemente pequeñas, de tal forma que el nuevo transductor puede usarse en lugar del goniómetro manual tradicional. El sistema está compuesto del dispositivo, la interfaz electrónica y la interfase gráfica de usuario MULTIELGON GUI. El dispositivo consiste de 14 transductores de ángulo-voltaje que se fijan a las pequeñas articulaciones de los dedos de la mano a través de una abrazadera de PVC y un guante elástico. El MULTIELGON se puede utilizar para evaluar la funcionalidad de la mano de los pacientes, así como registrar y manejar las mediciones ROM con propósito de seguimiento quirúrgico y decisiones en la terapia de rehabilitación.

Palabras clave. *Bland-Altman. Goniómetro. Cinemática humana. ROM.*

INTRODUCTION

The dexterity of the human hand is a fundamental attribute that enables a person to manipulate objects and convey information. In fact, the fingers of the hand are sufficiently vital in human performance that amputation at the metacarpophalangeal joint level is considered as a 54% impairment of an entire individual.[1] Temporal invalidity due to the presence of various pathologies or lesions is notably common and often causes disability. The Instituto Mexicano del Seguro Social (IMSS) reported that hand injuries occurring in 2010 accounted for 37% of industrial accidents.[2] Moreover, the Instituto Nacional de Rehabilitación (INR) stated that hand surgeries represented 18.45% of all orthopedic surgeries performed in 2010 and commonly the injuries affected the dominant hand.[3]

Physicians often evaluate digital function or hand symptoms by observing simple tasks, such as buttoning clothes, opening a safety pin or handling common tools. Physicians also examine patients concerning how they feel, requesting that they complete written questionnaires, fill in diagrams of where there is discomfort; and performing clinical tests; such as Tinel's Sign, Phalen's Test, the Semmes–Weinstein Test, and/or the Durkan Compression Tests. However, these assessments are highly subjective; the sensitivities and specificities depend on the level of training of the person collecting the data. If these tests are administered by inadequately trained individuals, the results can be inaccurate.[4]

Range of motion (ROM) refers to the distance and direction that a joint can move between the flexed and extended position. Limited ROM refers to a joint that has a reduction in its ability to move. Functional ROM evaluation of hand joints is crucial for developing effective rehabilitation programs, thereby avoiding long-term disability and decreasing the number of days taken off work by patients who have experienced an industrial accident. Furthermore, quantitative ROM evaluations can serve as baseline references for diagnosing functional impairment, as well as evaluating rehabilitative progress or surgical success.

Literature on the quantitative functional assessment of finger, hand and wrist joints is limited. Video-based or electromagnetic motion analysis systems have been extensively applied in gait analysis (gait is the pattern of walking, stepping or running and the style employed in these movements), shoulder kinematics, knee joint evaluation and lower limb or hip joint mechanical behavior.[5-7] These gait devices are not adequate for evaluating the hand's small finger joints on line, and they are impractical when studies for outpatient are required. Cerveri, *et al.*[8,9] have proposed hand kinematical models that describe motion during different hand tasks; several of these studies have used two non-orthogonal and non-intersecting rotational axes to quantify the motion of the human trapezio-metacarpal joint. Cheze and Dumas have worked in thumb kinematics[10,11] as well as in the standardization of terms that define the complex movements of joints.[12]

Kinematic analysis of human hand constraints includes range of motion (ROM) of the finger joints. The American Society for Surgery of the Hand (ASSH) has issued at E-HAND.COM[13] the standard amplitude values that can be expected while performing everyday activities for the proximal interphalangeal (PIP), distal interphalangeal (DIP), abduction (ABD), adduction (ADD) and metacarpophalangeal (MCP) articulations among others.

The main device used to measure ROM in the clinic is the manual goniometer, which utilizes a stationary arm, protractor, fulcrum, and movement arm to measure angles from the axis of the joint.[14] This device is not only tedious and time-consuming to use (Figure 1) but also is impractical for evaluating severely disabled hands.[15] Although the manual goniometers currently on the market (ISOM, Smith-Nephew, Digito) have good resolution (2°, 5° and 10°), the repeatability (variance due to equipment

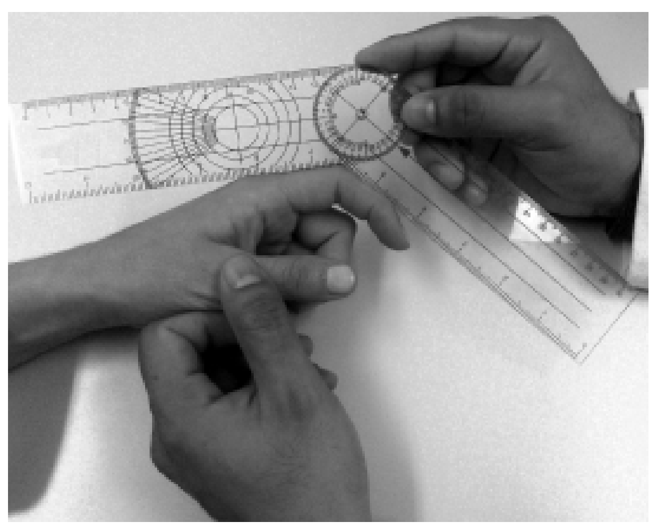

Figure 1. Manual Goniometer placement requires the skill of the examiner and it is only possible to measure an angle at a time.

variation) and reproducibility (variance due to different operators or appraiser variation which represents the incremental bias attributed to each operator's testing technique) of the measurements depend entirely on the examiner's experience.[16] Today, electronic goniometers are available in two or three sizes for measuring joints of both the upper and lower limbs; these goniometers are appropriately 1° in resolution, and ROM (0° to 270°) and meter reading is digital.[17] Electronic goniometers have the same limitations as manual goniometers:

- It is time-consuming to correctly place the device on the joint.
- It is not possible to perform multiple measurements simultaneously, and
- The device does not automatically adapt to the different sized joints in the hand.

Data gloves based on potentiometric, accelerometer or optoelectronic[18] principles had been designed to evaluate hand joint kinematics and identify the temporal synergies of different finger motions to eliminate subjective interpretation, reduce examiner inconsistencies and automate hand-motion capture or semi-automated goniometric measurements.[19] However, the reliability and accuracy of the measurements by these mechanisms remain questionable.[20] In addition, the mechanisms are impractical for clinical use because calibration is tedious, highly time-consuming and requires a high degree of skill. These mechanisms have mainly been applied in developing products and systems, such as hand prosthetics, hand-held tools, robotic hands, virtual reality,[21] gestic-interpreting[22] and tele-operation devices for physical therapy.

Despite the many papers investigating finger movements,[23] the assessment and monitoring of hand injuries during recovery are still deficient procedures in clinics due to the complicated structure of the hand and the difficulty of measuring the real joint angle of the fingers in motion using multi-cameras systems.

The lack of objective, quantifiable, reproducible and repeatable ROM data on the hand has hampered physicians' screening procedure to interpret and evaluate changes in hand functionality over time for surgery, rehabilitation, and return-to-work decisions. This paper proposes a new system, the MULTIELGON, which uses a novel angle-to-voltage transducer to improve upon the previous instrumented gloves to measure the range of motion of the human hand.

MATERIAL AND METHODS

Design of the system

The MULTIELGON system is composed of three main parts:

- An angle-to-voltage transducer based on Trim-Pot 82PR20K, which is a potentiometer or electrical variable resistor with three terminals; one terminal is connected to a sliding brush across the resistance element, dividing it into two resistors. This three-terminal potentiometer is used with one terminal connected to the wiper that is connected to a low voltage (5 V) DC voltage-divider circuit. The output voltage (V1 to V14) is directly proportional to resistence (R1-R14) and represents the angle of flexion or extension of the finger joints. The output voltage is characterized in the operating range.
  The angle-to-voltage transducer is attached to the finger through the PVC mounting clamp.
- The MULTIELGON device (patent pending) consists of 14 specific potentiometric angle-to-voltage transducers and an electronic interface. The device has five MCP transducers, five PIP transducers and four DIP transducers. The transducers placed on the human hand are shown in figure 2, MCP transducer is number 1, PIP transducer is number 2 and DIP transducer is number 3. The impedance of each angle-voltage transducer is connected to an electronic multi-

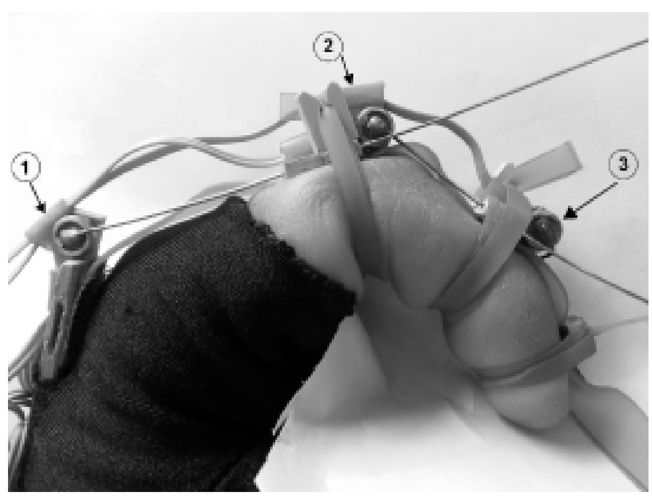

Figure 2. PIP, DIP and MCP angle-to-voltage transducers are placed on the joints of the fingers. 1. A MCP transducer. 2. A PIP transducer. 3. A DIP transducer. The transducers are based on Trim-Pot 82PR20K and they are attached to finger by a PVC clamp.

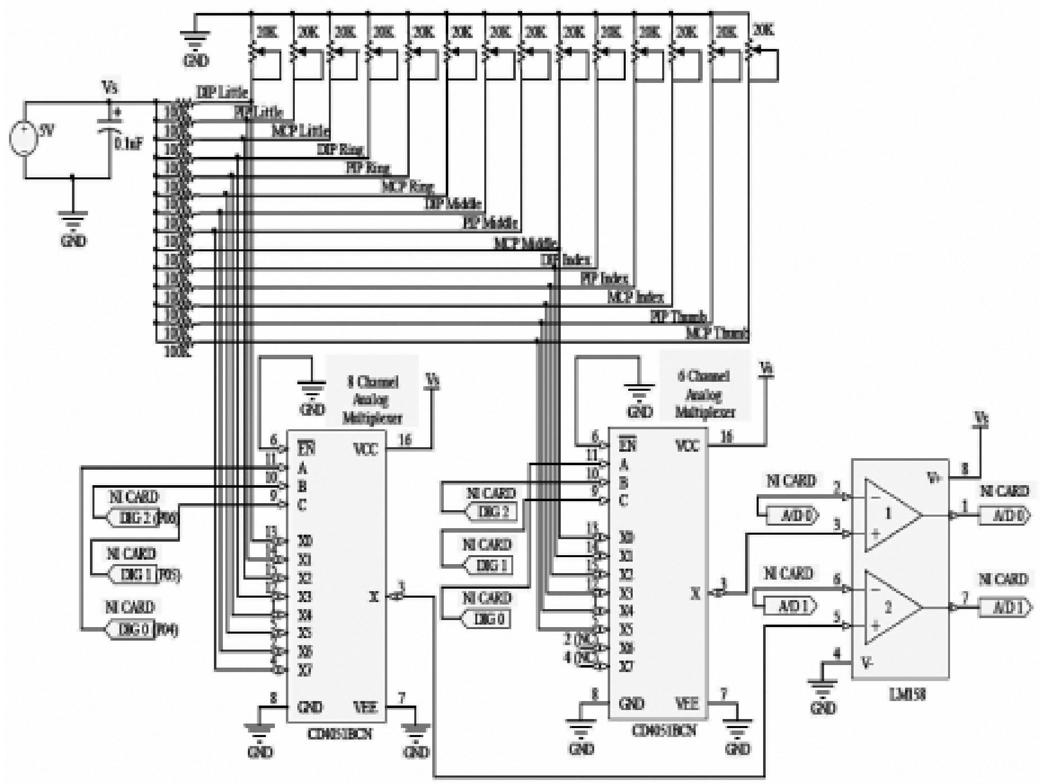

Figure 3. Electronic Interface. The fourteen voltages from each angle-voltage transducer are connected to two CD4051™ analog multiplexer/demultiplexers each output is coupled by two operational amplifiers (LM324™) towards the analog/digital converter NI PXI6122.

plexor, formed by two single 8-channel analog multiplexer/demultiplexers (CD4051™), each output is coupled using two operational amplifiers (LM324™), in buffer configuration, towards the multifunction data acquisition board NI PXI6122™, which digitizes the analog voltage outputs (Figure 3).

- The application software, or graphical user interface (MULTIELGON GUI), is designed to acquire and process ROM data, as well as generate a text-document report and archive data using the graph programming language LabView and DataBase National Instrument™. Fourteen streams of ROM data for MCP, PIP and DIP joints are captured and displayed simultaneously when the user presses the acquisition button. MULTIELGON GUI is programmed to determine the angles according to the number of joints; we can select one specific finger and joints to measure the angle, as well as the sampling frequency, number of measurements and study duration and intervals. ROM data must be stored and exported in EXCEL format.

Assessment of the system

- **Analysis.**

Two methods are included: the first is the statistical analysis which is used to evaluate the sensibility, accuracy, repeatability and reproducibility of the angle-to-voltage transducer. Sensitivity is the rate of change of voltage with respect to angular displacement ($dv/d\theta$), and accuracy is based on the standard deviation of the differences of angles between the transducer and a manual goniometer; these are determined by equation 1 and equation 2, respectively.

(1) Sensitivity = Mean ($Vn/\theta n$)

(2) Accuracy = $1 - \sigma z$

Where,

σ_z: standard deviation of z, and $z = (y_n - x_n)/x_n$.

x_n: goniometer measurement, and yn: transducer measurement.

V_n: voltage, and θn: angular displacement measure in electronic interface.

Measurements with the same examiner and instrument were used to evaluate repeatability, and measurements using the same instrument but different examiner were employed to determine reproducibility. Only the first measurements by each method are used to illustrate the comparison of methods; the second measurements are employed to study repeatability. We use the Range and Mean Method based on ANOVA analysis described by Botero, *et al.*[24] to calculate the instrumentation variability or repeatability and operator variation or reproducibility, given by equation 3 and equation 4, respectively. These equations provide an estimate for device and operator variability.

$$dv = \frac{\overline{R}}{d_2} \quad (3)$$

$$ov = \frac{\overline{Ro}}{d_2} = \frac{\overline{R} - \overline{RR}}{d_2} \quad (4)$$

Where,

dv: Device variation.
ov: Operator variation, and
$\overline{R}$ and $\overline{RR}$: individual average for each operator.
R_o: Difference between the total average for each operator.
d_2: Constant based on standard deviation considering the number of trials and the number of ranges.[25]

The second analysis is the Bland-Altman[26] plot, or Difference plot, is a method of plotting data used in medical statistics to analyze agreement between two assays. This plot compares a new measurement technique with the gold standard to determine if the new technique agrees with the gold standard. This type of plot helps assess the magnitude of disagreement (or bias) and determine if any trends exist. It is expected that if the differences are normally distributed (Gaussian), 95% of differences will lie between the limits of agreement (mean of differences ± 1.96 SD). Thus, the bias (estimated by the mean difference and the standard deviation of the differences) is small; the two methods can be used interchangeably, or the new technique can replace the established one.

- **Techniques to capture measurements.**

The manual goniometer (Smith-Nephew™) is used to evaluate the sensibility, accuracy, repeatability and reproducibility of the angle-to-voltage transducer. This element is aligned to the 0° position over the manual goniometer to establish the zero value, the center contact of the transducer is moves from -20° (or 20° extension) to 110°. The output voltage V is measured every 1° (sample size, 130 angles) from -20° to 110°. Ten samples for each angle and two trained operators are selected to perform the measurement test. The first operator measures the samples in random order and the second operator measures the samples in the same order as the first operator without viewing the results of the first operator.

The Bland-Altman method is used to evaluate if the MULTIELGON system agrees with the manual goniometer (gold standard), involves twenty volunteers, ten female and ten male aged 22-55 years without any neuromusculoskeletal finger injuries. Fourteen angle-to-voltage transducers, using four DIP, five PIP and five MCP items, are attached to the dorsal surface of the fingers joints (index, middle, ring, little and thumb) of each subject for collecting motion data. The transducers are arranged as follows: first, a segment is formed by the first PIP and MCP transducers for the thumb, the 1st PIP transducer is placed 1 cm distal to the fingertip, and the 1st MCP transducer is placed 1 cm distal to the PIP joint of the thumb. The second segment array includes the 2nd, 3rd, 4th and 5th MCP transducers are attached to the dorsal side of the metacarpophalangeal joint. The third segment array including the 2nd, 3rd, 4th and 5th PIP transducers are attached to the dorsal side of the proximal joint of the index, middle, ring and little finger. Lastly, the fourth segment array comprising the 1st, 2nd, 3rd and 4th DIP transducers are attached to the dorsal side of the distal phalanx at 1 cm for each fingertip. Both the 14 transducers and the electrical interface are attached to the back of the hand, the first through a Lycra glove with slots where the PVC mounting elements are inserted, and the second being attached via a connector embedded in synthetic rubber. The testing procedure was explained to every subject prior to the experiment. All movements begin in a seated posture with the subject's torso upright, upper arm vertical and forearm horizontal on an armrest; the hand is outstretched, and the palm faces medially. The subjects carry out the following three passive tasks:

- The hand is placed on the table in neutral position (0°) with the palm down for calibrating data.
- Flexion movements from 0° to 110°, and
- Extension movements from 0° to -20°.

All measurements were recorded simultaneously with MULTIELGON GUI. Two sets of measurements (65 values) were compared, one made with the manual goniometer (Smith-Nephew™ resolution 2°, considered as the gold standard), method A, and the other with the angle-to-voltage transducer, method B. The Bland-Altman method is used to calculate the difference (A-B) between the two measurement techniques against (A+B)/2, the average.

RESULTS

A total of 1,680 measurements were processed through analysis of variance to compare the differences, means and coefficient of correlation for two groups, females (n = 840) and males (n = 840). Table 1 shows the measurements of resistance, voltage and angle, which were used to assess the following characteristics of the angle-to-voltage transducer: repeatability (transducer variation is less to ± 0.47°), reproducibility (operator variation is less to ± 1.94°), accuracy (92.5%) and sensibility (4 mV/°). Table 2 shows the mean and standard deviation, which were compared with the normal hand ROM measurements found in the literature.[13]

We found low dispersion [standard deviation ($5e\text{-}3 < \sigma < 325e\text{-}^{3}$)] and high homogeneity [variance ($2.55e\text{-}^{5} < \sigma^2 < 105e\text{-}^{3}$)] of measurements relative to the average within the range of -20° to 110° with 0.1° of resolution. The correlation coefficient, r, is 0.9995.

The figure 4 describes the transducer's linear behavior. To reduce the error, the output voltage (V)

Table 1. Sample of measurements (resistance and voltage) for operator 1 and operator 2, to calculate repeatability, reproducibility and accuracy of the potentiometric angle-to-voltage transducer.

n	Goniometer x_n (°) Y_{nm}	Transducter (operator 1) Angle R_{nm}(kΩ)	Resistance V_{nm}(mv)	Voltage	$Z_{nm} = Y_{nm}\text{-}X_{nm}/X_{nm}$	Range (°) Operator 1 $Ra_{nm}/\overline{RA}_n$	Operator 2 $RRA_{nm}/\overline{RRA}_n$
1	100	$109.18_{1,1}$	$2.522_{1,1}$	$110_{1,1}$	$0.0074_{1,1}$	$RA_{1,1} = 0.82$	$RA_{1,1} = 3.45$
		$110.56_{1,2}$	$2.534_{1,2}$	$111_{1,2}$	$0.0051_{1,2}$	$RA_{1,2} = 0.56$	$RA_{1,2} = 5.87$
		$109.31_{1,3}$	$2.376_{1,3}$	$110_{1,3}$	$0.0062_{1,3}$	$RA_{1,3} = 0.69$	$RA_{1,3} = 1.23$
		$110.53_{1,4}$	$2.525_{1,4}$	$109_{1,4}$	$0.0048_{1,4}$	$RA_{1,4} = 0.53$	$RA_{1,4} = 3.15$
		$110.48_{1,5}$	$2.407_{1,5}$	$113_{1,5}$	$1.0043_{1,5}$	$RA_{1,5} = 0.48$	$RA_{1,5} = 2.95$
		$109.34_{1,6}$	$2.427_{1,6}$	$108_{1,6}$	$0.006_{1,6}$	$RA_{1,6} = 0.66$	$RA_{1,6} = 3.89$
		$110.53_{1,7}$	$2.387_{1,7}$	$112_{1,7}$	$0.004_{1,7}$	$RA_{1,7} = 0.53$	$RA_{1,7} = 2.3$
		$110.48_{1,8}$	$2,414_{1,8}$	$107_{1,8}$	$0.004_{1,8}$	$RA_{1,8} = 0.48$	$RA_{1,8} = 1.9$
		$110.34_{1,9}$	$2,427_{1,9}$	$108_{1,9}$	$0.0031_{1,9}$	$RA_{1,9} = 0.34$	$RA_{1,9} = 4.55$
		$110.48_{1,10}$	$2.414_{1,10}$	$111_{1,10}$	$0.0043_{1,10}$	$RA_{1,10} = 0.48$	$RA_{1,10} = 3.56$
						$\overline{RA}_1 = 0.57$	$\overline{RRA}_1 = 3.28$
5	106	$107.86_{5,1}$	$2.758_{5,1}$	$121_{5,1}$	$0.001_{5,1}$	$\overline{RA}_5 = 0.49$	$\overline{RRA}_5 = 3.53$
11	100	$98.90_{11,1}$	$3.726_{11,1}$	$152_{11,1}$	$0.011_{11,1}$	$\overline{RA}_{11} = 1.12$	$\overline{RRA}_{11} = 5.49$
65	44	$44.73_{65,1}$	$8.43_{65,1}$	$378_{65,1}$	$0.006_{65,1}$	$\overline{RA}_{65} = 1.32$	$\overline{RRA}_{65} = 2.25$
69	40	$38.42_{69,1}$	$8.969_{69,1}$	$408_{69,1}$	$0.027_{69,1}$	$\overline{RA}_{69} = 0.89$	$\overline{RRA}_{69} = 1.09$
74	35	$35.68_{74,1}$	$9.435_{74,1}$	$421_{74,1}$	$0.009_{74,1}$	$\overline{RA}_{74} = 0.55$	$\overline{RRA}_{74} = 2.25$
120	-10	$-11.78_{120,1}$	$11.78_{120,1}$	$11.78_{120,1}$	$0.022_{120,1}$	$\overline{RA}_{120} = 0.47$	$\overline{RRA}_{120} = 3.79$
125	-15	$-16.46_{125,1}$	$16.46_{125,1}$	$16.46_{125,1}$	$0.036_{125,1}$	$\overline{RA}_{125} = 0.66$	$\overline{RRA}_{125} = 4.48$
130	-20	$-18.76_{130,1}$	$18.76_{130,1}$	$18.76_{130,1}$	$0.062_{130,1}$	$\overline{RA}_{130} = 1.23$	$\overline{RRA}_{130} = 5.69$
						1.35°	$\overline{\overline{RA}}$
						4.18°	$\overline{\overline{RRA}}$
						2.85	d2*
	Inaccuracy = σ_z	0.047				0.47°	*dv*
	Accuracy = $1\text{-}\sigma_Z$	0.953				1.94°	*ov*

Table for d2* is a statistical constant based on standard deviation considering the number of trials and the number of ranges calculated multiplied by the number of operators. Values may be found in Duncan.[25] n: number of trials (10). RA: is the absolute vale of the difference between the value obtained between X_n and Y_{nm} for the operator 1 and RAA for operator 2. Y_{nm}, R_{nm}, V_{nm} shown for operator 1.

in the transducer was linearized with the relationship of the equation 5.

(5) $V = -0.004\,\theta + 0.558$

Where θ is the angular displacement.

Table 2. Mean and Standard Deviation for PIP, DIP and MCP measurements acquired with MULTIELGON and compared with ASSH values for flexion movements for healthy male and female subjects.

Joint	Finger	ASSH[9]	MULTIELGON Mean (σ)	
		Range	Male	Female
PIP	Thumb	-15 to 80°	65° (3.74)	78.36° (11.1)
	Index	-10 to 100°	86.6° (6.55)	87° (5.03)
	Medium	-10 to 100°	85.08° (5.88)	86.51° (5.6)
	Ring	-10 to 100°	93.67° (2.96)	90.2° (7.7)
	Little	-10 to 100°	91.81° (17.34)	84.9° (11.5)
DIP	Index	-10 to 80°	57.95° (15.04)	63.9° (10.6)
	Medium	-10 to 80°	55.62° (5.85)	58.47° (9.2)
	Ring	-10 to 80°	58.43° (18.86)	68.3° (10.3)
	Little	-10 to 80°	56.71° (8.53°)	48.18° (5.9)
MCP				
	Thumb	-10 to 55°	57.27° (6.14)	62.8° (7.75)
	Index	-10 to 90°	49.2° (5.31)	53.05° (8.8)
	Medium	-10 to 90°	66.33° (5.92)	61.1° (8.55)
	Ring	-10 to 90°	65.3° (1.62)	59.9° (8.46)
	Little	-10 to 90°	52.76° (3.7)	57.24° (6.5)

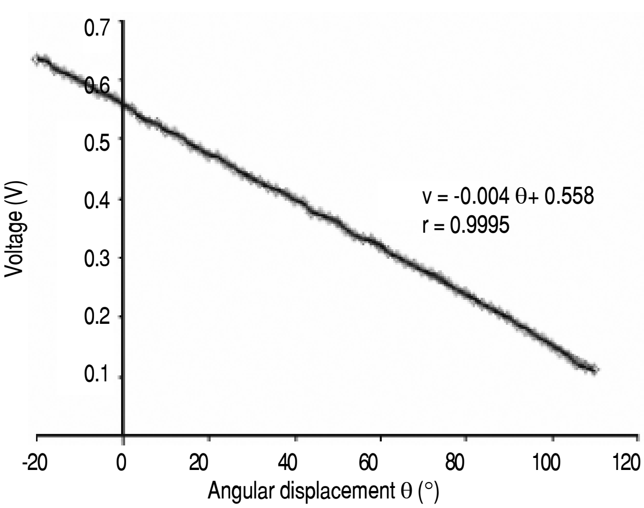

Figure 4. The graph shows the linear relationship between the angular displacement vs. *the transducer's output voltage.*

Figure 5 illustrates the plot of differences (method A - method B) against averages of the angles (method A by method B) when the Bland-Altman method was applied. The graph shows 36% of the data around the line of equality (differences = 0). The 95% limits of agreement (-1.7°, 1.4°) contain 95% (122/128) of difference scores. The mean of differences (bias) of the measurements between the transducer and manual goniometer method is $\bar{d}$ = 0.14°. The SD of the differences is 0.77, and the width of the 95% limits of agreement is 3.1°.

The difference values are normally distributed (Gaussian), that is, approximately 68% of differences (87/128) are within one standard deviation of the mean. Approximately 95% are within two standard deviations (122/129), and nearly 99.7% are within three standard deviations (127/128).

Because the limits of agreement are only estimates, we use the standard error of the mean (SEM) and standard of error of the limits of agreement (SELA) calculated by equation (6) and equation (7), respectively, to determine the precision of our estimates.

(6) $$SEM = \sqrt{SD^2/n}$$

(7) $$SELA = \sqrt{3\,(SD^2/n)}$$

Where n is the sample size, and SD_2 is the standard deviation of the differences.

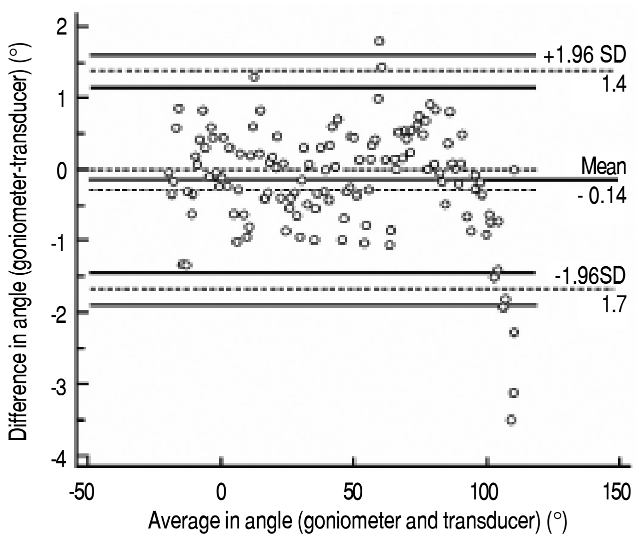

Figure 5. Bland-Altman plot. Differences of angles measured by the manual goniometer and the angle-to-voltage transducer are drawn against the mean of the paired measurements. The 95% limits of agreement (-1.7°, 1.4°) contain 95% (122/128) of difference scores and are within two standard deviations (122/129).

The 95% confidence interval (CI) is calculated by finding the point of the t distribution24, with n-1 degrees of freedom (sample size - 1) and adding/subtracting of the t standard error. For the angle data, SD is 0.77, the SEM is 0.096, and the SELA is 0.1667°. For the 95% CI, we have 63 degrees of freedom, and t = 2.01. Hence, the 95% CI for the bias is -$\bar{d}$ ± (t x SEM), giving -0.329° to 0.049°. The 95% CI for the lower limit (LL) of agreement is -LL ± (t x SELA), giving -2.035° to -1.36°. For the upper limit (UL) of agreement, the 95% CI is -UL ± (t x SELA), giving 1.065° to 1.735°.

DISCUSSION

The MULTIELGON can be used by a trained therapist easily and quickly. This device only requires attaching the transducer to each joint by means of an elastic rubber band and can automatically acquire up to 14 ROM measurements simultaneously at the press of the acquisition button. The advantages of the MULTIELGON are particularly beneficial for evaluating patients with deformed hands. The size and shape of the fingers of every individual is unique, and the transducers can be placed regardless of the degree of finger deformation.

Full calibration of the device is easy, fast and practical. The hand is placed on a hard flat horizontal surface in an outstretched position with the palm down. At this point, the calibration button is pressed, and the basal measurements are set as the zero value (0°). Thus, we can obtain flexion and extension values relative to the zero of each subject. The optimal transducer placement over the joint assures that the mechanical axis is parallel to each finger.

The device is reliable; the error due to transducer variation (repeatability ± 0.47°) is negligible within the operation range. However, there was an incremental bias of 1.94° attributed to each operator. Therefore, errors due to the repeatability and reproducibility will not affect the diagnosis of the patient. Thus, the device can be used for clinical purposes.

A particular angle-to-voltage transducer was designed for each joint type: the MCP item, PIP item and DIP item. Each of these transducer types was assessed; all of the types had low dispersion and high homogeneity within the range of -20° to 110° with 0.5° of resolution. After the precision, reliability and accuracy of each transducer was checked, the MULTIELGON device was assembled.

The results generated by the two instruments (transducer of the MULTIELGON and manual goniometer) were inspected to compare performance. The correlation coefficient was very high (0.9995), while the mean of differences between the measurements was nearly zero (-0.14), describing a linear relationship.

According to the Bland-Altman analysis, the limits of agreement (1.4° and -1.7°) of the 95% CI of the two instruments differed by less than 3.1°, and these instruments did not vary in any systematic manner throughout the range of measurement.

The 95% CI for the lower limit of agreement (-2.035° to -1.36°) and upper limit of agreement (1.065° to 1.735°) were small enough to assume that the new method can be used in place of the old method. The two methods show little variation of the differences, low discrepancies between the two meters and an acceptable degree of agreement.

The differences were sufficiently small that the physician is able to use the MULTIELGON in place of the manual goniometer for clinical purposes. These instruments can be used interchangeably because the small difference would not affect decisions regarding patient management.

Currently, we are working to determine the basis of the MULTIELGON as a normal electronic ROM instrument by observing several pairs of hands. Additionally, we would like to obtain standard measurements for both before and after surgery that can be used to monitor improvement in hand functionality.

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The tenets of the Declaration of Helsinki were observed, and the study was approved in advance to the collection and use of data by the Ethics Committee of the Instituto Nacional de Rehabilitación in Mexico City (reference number 06-09), where the work was carried out. Informed consent was obtained from participants after that nature (non-invasive, no risk, scope, confidentiality) of the study had been fully explained. The authors declare that no conflict of interest exists.

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