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INNOVATION

Development, validity and reliability of a new pressure air biofeedback device (PAB) for measuring isometric extension strength of the lumbar spine

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ABSTRACT

This study describes the development of a new portable muscle testing device, using air pressure as a biofeedback and strength testing tool. For this purpose, a pressure air biofeedback device (PAB®) was developed to measure and record the isometric extension strength of the lumbar multifidus muscle in asymptomatic and low back pain (LBP) persons. A total of 42 subjects (age 47.58 years, ±18.58) participated in this study. The validity of PAB® was assessed by comparing a selected measure, air pressure force in millibar (mb), to a standard criterion; calibrated weights in kilograms (kg) during day-to-day tests. Furthermore, clinical trial-to-trial and day-to-day tests of maximum voluntary isometric contraction (MVIC) of L5 lumbar multifidus were done to compare air pressure force (mb) to electromyography (EMG) in microvolt (μV) and to measure the reliability of PAB®. A highly significant relationship were found between air pressure output (mb) and calibrated weights (kg). In addition, Pearson correlation calculations showed a significant relationship between PAB® force (mb) and EMG activity (μV) for all subjects ($n = 42$) examined, as well as for the asymptomatic group ($n = 24$). No relationship was detected for the LBP group ($n = 18$). In terms of lumbar extension strength, we found that asymptomatic subjects were significantly stronger than LBP subjects. The results of the PAB® test differentiated between LBP and asymptomatic subject's lumbar isometric extension strength without any risk to the subjects and also indicate that the lumbar isometric extension test with the new PAB® device is reliable and valid.

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PAB®; air pressure; isometric strength; low back pain (LBP); reliability

1. Introduction

Worldwide, low back pain (LBP) is the most prevalent pain disorder, affecting about 9.4% of the global population.[1] A global review indicated a one-month prevalence of 23%, a one-year prevalence of 38% and a lifetime prevalence of about 40% in the general adult population.[2] To address this problem, it is important to rehabilitate the muscles that provide the majority of the strength needed to stabilise and protect the lumbar spine.[3,4] Because day-to-day activities regularly depend on muscular strength, the accurate assessment of lumbar muscle function in LBP patients is essential in guiding the rehabilitation professional to monitor the effect of various rehabilitation interventions.[3,4] However, measuring muscle strength in a simple and scientific way has become problematic in that muscle strength measuring instruments are often too bulky, too expensive and/or too cumbersome to operate.[5] This is why several researchers, over the last 30 years, developed or tested different portable muscle testing devices for use in the clinical office setting.[5–8] Of particular importance would be the development of a muscle testing device that is reliable and valid and according to Li et al.,[9] would represent a technical advance in portable muscle strength devices that provide comparable information to those obtained by isokinetic dynamometers at a fraction of the cost and size. Furthermore, if a person is unable to perform a dynamic exercise due to an injury or pain in certain range of joint movements, then isometric testing is a reliable, alternative method of muscle strength testing.[10] Various isometric strength tests have been shown to be highly reliable as assessed by reliability coefficients.[11–13] Apart from been reliable, the other factors that drove the need for developing the PAB® device were the following: (a) the device had to be portable, (b) simple to operate, (c) inexpensive, (d) valid and (e) should be used for "strong man and old lady testing".[14,15] The purpose of this study was to develop a pressure air

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biofeedback device (PAB®), capable of accurately recording the isometric contraction of the L5 lumbar multifidus muscle in a closed chain, seated back extension test. The development of the PAB® software program aimed to analyse the recorded pressure air force graph, in order to provide feedback regarding certain parameters like: maximal isometric strength and pressure force comparisons with calibrated weights. The PAB® device was developed to be used in a home or clinical office testing environment.

2. Methods

2.1. Description of the PAB® device

The PAB® device can be described as an isometric muscle testing device which consists of an air-filled elastic ball (± 22 cm in diameter), which is inflated to a pre-determined internal pressure. The air-filled ball is partially enclosed within two rigid (fibreglass) shell capsules that fit on opposite outer surfaces of the ball. The rigid shell capsules are joined together by a 9 cm non-elastic, nylon Velcro strap. Another 9 cm nylon Velcro strap, which acts as a handle or torso strap, attaches and extends from the primary strap on one side, through which the torso can be placed. On the other side, a light chain and steel pipe attach and extend from the primary strap for both feet to push against. By pulling the chain and torso strap attachments away from one another, the primary strap pulls the shell capsules towards one another (direct compression), thereby increasing the air pressure in the ball (Figure 1). These volume changes are then registered by the pressure transducer and communicated to and reflected on the personal computer (PC) screen.

The pressure monitoring system of the PAB® device includes a pressure sensor called the Druck PMP 1400 (General Electric) that is connected in communication with the internal space of the ball via Festo tubing (Festo AG & Co.KG, Esslingen). An air hand pump is connected in line with the Festo tubing to adjust the baseline internal pressure (mb) of the ball. The pressure transducer electronically connects to a personal computer to provide a visual (biofeedback) and/or printed record of pressure changes within the ball during the performance of muscle strength testing (Figure 1). Sample rate of logged recording was 10 milliseconds. Connection to transducer interface is done using Ethernet connection at 100 Megabits per second.[16] The application has been custom designed and written in C++ Builder from Borland Corporation. All data is stored in MSSQL database. The mb unit has been chosen, firstly, because it is more sensitive by measuring air pressure as raw data, secondly, from a practical point of view, it gives better visual feedback to subjects and thirdly, calibration is more precise in smaller units.

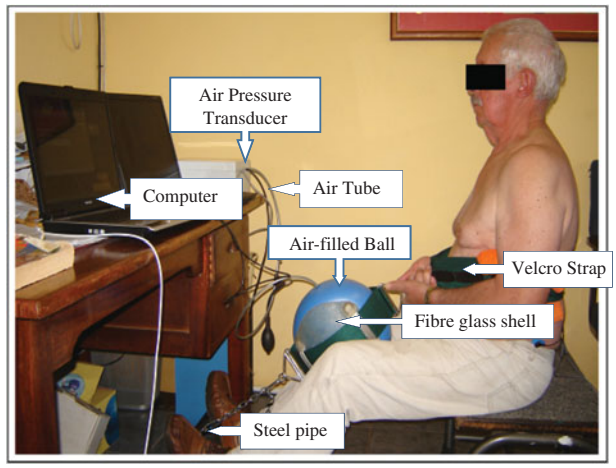

Figure 1. The PAB device set-up during the back extension test.

2.2. Subjects

In this study, subjects participated of their own free will and were randomly selected from asymptomatic persons as well as LBP persons. Twenty-four (24) asymptomatic subjects of 12 females and 12 males, mean age 46.64 years (± 21.43) as well as 18 LBP subjects of 9 males and 9 females, mean age 48.89 years (± 14.22) were recruited from the clientele of a local health club, as well as a Biokinetic practice situated in the city of Pietermaritzburg, South Africa. Anthropometry data of the male subjects ($n = 21$) indicated a mean body mass of 80.51 kg (± 11.50) and a mean height of 1.76 m (± 0.08), while the female subjects mean body mass was 65.1 kg (± 13.39) with a mean height of 1.64m (± 0.06). All 42 subjects gave their written, voluntary consent. For an evaluation device to be used in clinical practice and be clinically relevant, it is important that symptomatic individuals be included in validation studies of newly developed medical instruments.[14,17] Therefore, it was decided to include asymptomatic as well as LBP subjects, to assess the clinical usefulness of the PAB® device. The study was approved by the Stellenbosch University Ethics Committee.

2.3. PAB® device calibration

Pneumatic manometers do not measure with the same units of measurement as isokinetic or isometric

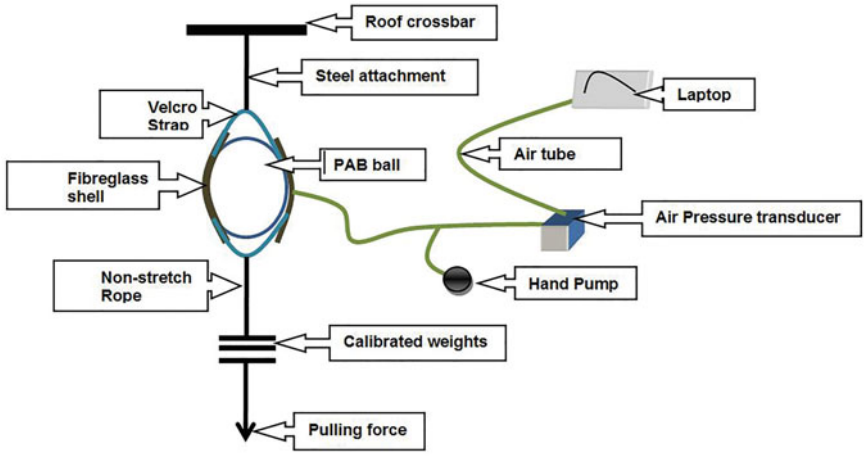

Figure 2. Calibration technique of the PAB device.

dynamometers, which make comparisons between these instruments problematic.[18] However, this technical problem was solved by Axen et al. [6] and Helewa et al. [7] by using incremental calibrated weights in kilograms (kg) to compress a sphygmomanometer bag and/or elastic ball to determine if a linear relationship existed between the applied external force (kg) and internal pressure of the ball or sphygmomanometer. In the case of the PAB® device, a different calibration protocol was followed. Firstly, the applied calibrated weights (accurate within one gram as weighed on a calibrated physician's scale) were hanged from the PAB® ball, creating a pull-compression action on the PAB® ball from both sides by the rigid fibreglass capsules (Figure 2). This simulated the action of the back extension test. Secondly, the calibration procedure was done in 2.5 kg weight increments, between 2.5 and 160 kg, and was plotted against the corresponding internal pressure (mb) of the PAB® ball. In terms of the SI metric conversion, the air pressure output (mb) of the PAB® device may also be expressed as force in kilograms (kgf) or Newton, especially when muscle strength is expressed.[19]

2.4. Testing procedure

Two tests of maximal voluntary isometric contraction (MVIC) were done on day one and one MVIC was done on day two. Before EMG testing, the specific skin areas were properly cleaned with surgical alcohol. The L5 skin location was confirmed by palpating L4/5 interspinous space and L4 spinous process from the position of the iliac crests.[20] Two pairs of disposable, self-adhesive surface electrodes (Bluetrode, GP 00–50/D) were attached on the right and left side over the greatest convexity of the L5 multifidus.[21] A reference electrode was placed on the left lateral iliac crest. The raw EMG signal was recorded from the two electrode locations [Myotrace 400 (MT400), Noraxon, Scottsdale, AZ, USA] and stored on a personal computer using Myoresearch XP software. The sampling rate for the MT400 EMG device is 1000 samples per second (s). The root mean square (RMS) on the MT400 EMG display was reported and smoothed with a window of 300 milliseconds (ms).[22] After completing the preparation for EMG testing, the subject was asked to sit on a bench in an upright, neutral spine position.[3,23] The PAB® device and its attachments (Velcro strap, chain and steel pipe) were then fixed to the subject's body. Goniometric angles for the hips were set at approximately 90° flexion, while the knees where flexed close to 45°. A non-stretchable Velcro strap was fitted around the thorax, just below the inferior angles of the scapulae (dorsal view) and just below the mamilla line (frontal view). The subject was asked to perform two submaximal contractions in the seated neutral spine posture to become familiar with the PAB® device and the real-time biofeedback graph as shown on the computer screen. After a two-minute break, the research testing was started. The internal air pressure of the ball was always checked and if necessary calibrated at 50 mb before each test. The subject was instructed to sit relaxed in an upright neutral spine position while resting EMG was recorded over a five second period. The subject was then instructed to do two MVIC tests in neutral spine posture. The subject started with a two second build up to a maximum isometric extension effort and then held for three seconds at maximum, giving a total of five seconds. A one minute rest break was given between the two

MVIC tests. The best PAB® force output of the two tests was used as the maximum PAB® force. The PAB® and EMG data collected after each test was saved for analysis. Three PAB® recordings, as well as three EMG recordings each of the left and right m. lumbar multifidus were taken and then averaged. The same testing protocol was strictly followed for the second MVIC test on day two.

2.5. Statistical analysis

Instrument validity was assessed using the Pearson correlation coefficient (r) in order to examine the correlation between PAB® force (mb) and an applied external force (calibrated weights in kg). The intraclass correlation coefficient (ICC) and standard error of measurement were calculated between PAB® force values of the two calibration tests over the two days. Pearson correlation coefficients were also calculated between PAB® force (mb) and root mean square (RMS) values of EMG (μV) for the MVIC tests on day one and day two for the whole group ($n = 42$), the LBP group ($n = 18$) and asymptomatic group ($n = 24$). Also, repeated measures ANOVA were performed to determine the difference in low back strength, expressed in PAB® force (mb), between the LBP and asymptomatic group during MVIC. An alpha level of .05 was selected for statistical significance. Statistica software program was used for data analysis.

3. Results

3.1. Validity and reliability

The calibration results of PAB® force (mb) and applied external force comparisons (calibrated weights in kg) on day one are shown in Figure 3. A highly linear relationship emerged between PAB® force (mb) and the whole range of calibrated weights (kg) in the two calibration tests done on day one ($r = .995$, $p < .01$) and day two ($r = .998$, $p < .01$). A strong relationship ($r = .997$, $p < .01$) between average PAB® force data (mb), calculated over the two days in relation to calibrated weights, was also found. The calibration results demonstrated high agreement or validity between measures (calibrated weights in kg) and the associated criterion (PAB® force in mb). Furthermore, the ICC calculation of 0.997 (SEM =1.55) between the two sets of PAB® force calibration measurements between day one and two, indicated a significant correlation and therefore excellent reliability of the PAB® device.

3.2. Reliability

In terms of PAB® measurements ($n = 42$), the ICC agreement results of PAB® force at MVIC on day one calculated 0.99 (SEM = 4.44), while day two (MVIC) reported a similar result of 0.99 (SEM = 3.22). These results indicated very good reliability for the PAB® force values.

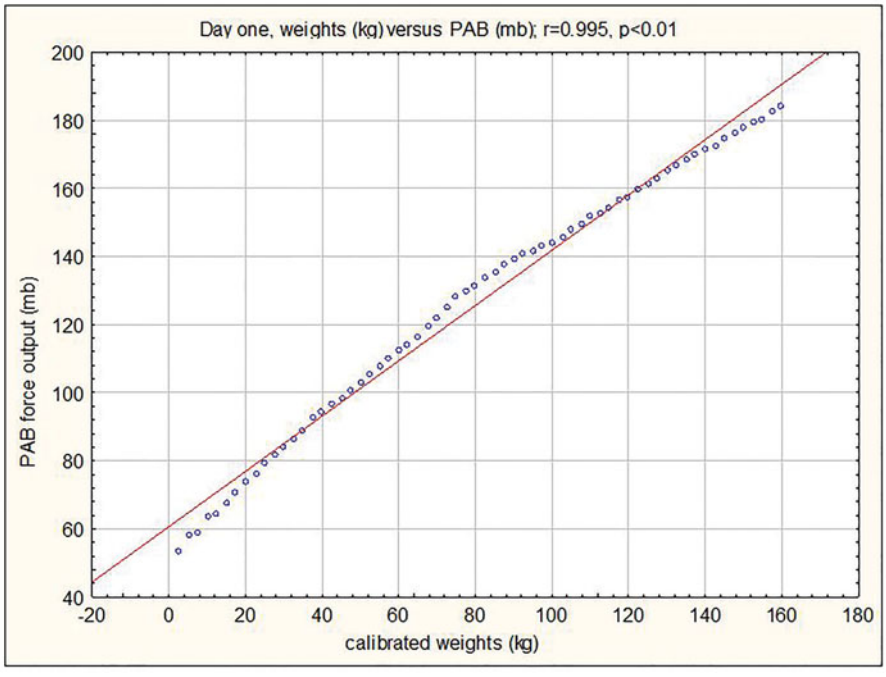

Figure 3. Correlation between PAB (mb) and calibrated weights (kg).

When comparing PAB® force (mb) to RMS values of EMG (μV), a significant correlation ($p < .01$) was calculated between EMG and PAB® values for the whole group ($n = 42$) and asymptomatic group ($n = 24$) for MVIC over the two days. However, day one and two results of MVIC measurements for the 18 LBP subjects indicated a non-significant correlation between EMG and PAB® (Table 1).

3.3. Lumbar extension strength

The lumbar extension strength of the asymptomatic subjects, reported a mean PAB® force pressure of 150.33 mb (±42.44) or 110 kgf at MVIC. The mean PAB® force pressure for LBP subjects was 108.24 mb (±20.99) or 57.5 kgf at MVIC, demonstrating a significant difference of 52.5 kgf ($p < .01$) between the two groups (Figure 4). These low back strength levels represented a 100% isometric effort or MVIC for both groups. With respect to the difference in lumbar extension strength between the two groups, the low back pain group lacked lumbar extension strength ($p < .01$) as measured at the L5 level, compared to the asymptomatic group. Therefore, the PAB® test appears to be a reliable and valid testing device to differentiate between the lumbar extension strength levels of LBP and asymptomatic subjects.

Table 1. Pearson correlation calculations between PAB (mb) and EMG (μV).

	Day one – EMG versus PAB		Day two – EMG versus PAB	
MVIC Test	Pearson (*r*)	*p* Values	Pearson (*r*)	*p* Values
Whole group ($n = 42$)	.75	.01	.63	.01
Asymptomatic group ($n = 24$)	.75	.01	.73	.01
LBP group ($n = 18$)	.26	.29	−.11	.68

4. Discussion

The test results of validity and reliability of the new PAB® device indicated that the isometric assessment of lumbar extension strength is accurate and reproducible. This strongly relates to the general observation that the isometric mode of strength testing has been shown to be highly reliable and is supported by various other research studies.[11–13,24] With respect to PAB® validity assessments, Pearson correlation coefficients (*r*) indicated that a significant linear relationship emerged between air pressure output (PAB® force in mb) and the whole range of applied external forces (calibrated kg weights) in the two calibration tests (test–retest). Secondly, the ICC calculation between the two sets of PAB® force calibration measurements between day one and two indicated a significant correlation and therefore excellent reliability of the PAB® device. Therefore, the results of PAB® force (mb) and applied external force comparisons (calibrated weights in kg) is in agreement with the results of a similar study where air pressure and calibrated weights were used as measurement units for neck muscle strength.[6] Thirdly, in terms of PAB® measurements (test-retest), the ICC agreement results of PAB®

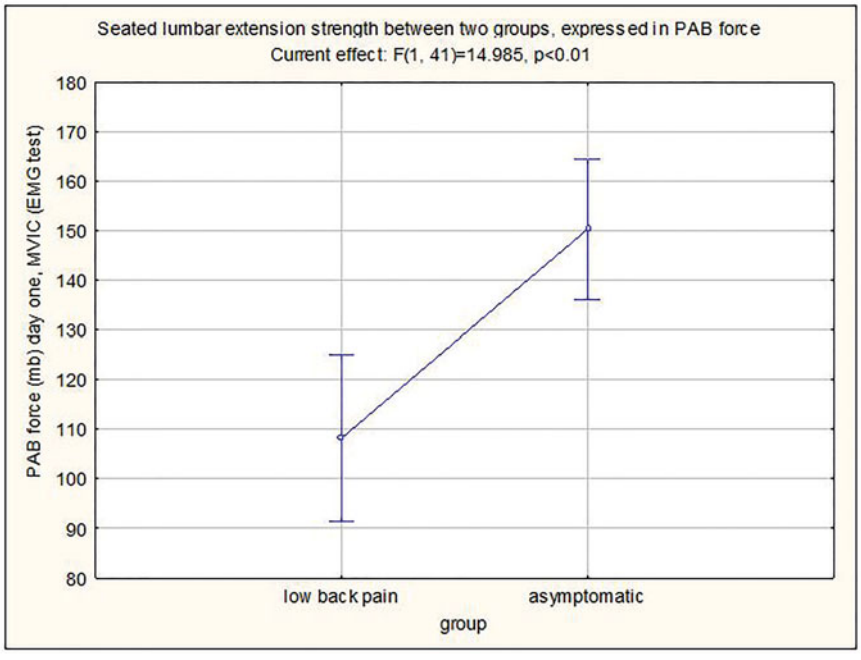

Figure 4. Low back strength between asymptomatic ($n = 24$) and LBP subjects ($n = 18$).

force at MVIC between day one and two indicated the reliability for the PAB® force values.

When comparing the RMS values of EMG (μV) and PAB® force results (mb) for the whole group ($n = 42$), a moderate to strong correlation ($p < .01$) for MVIC was achieved. This was arguably due to the low back pain group's ($n = 18$) highly non-significant EMG/PAB® force correlation ($p > .05$) achieved when compared in subgroups. More specifically, the m. lumbar multifidus EMG activity during MVIC testing in the LBP subjects indicated a significant non-linear relationship between the bioelectrical output (μV) and the PAB® force output (mb) of the m. lumbar multifidus. Clinically, it may be explained that 66.7% (12–18 subjects) of the LBP group experienced unilateral denervation of m. lumbar multifidus as shown in their real-time EMG graphs. Various other studies have also reported that chronic LBP patients have poorer muscle activation and greater muscle wasting of the m. lumbar multifidus compared to normal subjects and highlighted the importance of restoring m. lumbar multifidus activation and size.[21,25] When the asymptomatic group's ($n = 24$) data was analysed, the correlation between EMG activity and PAB® force indicated a significant linear relationship ($p < .01$). Similar linear relationships between increased EMG and increased muscle strength were also reported in various studies.[26,27] Therefore, the difference in m. lumbar multifidus EMG activity and PAB® force between the LBP and asymptomatic groups may indicate a normal stabilisation or anti-gravity contraction of m. lumbar multifidus in the asymptomatic group and dysfunction due to bioelectrical denervation of m. lumbar multifidus in the LBP group.[4,25,28] The difference in lumbar extension strength between asymptomatic and LBP subjects indicated a normal stabilisation contraction of m. lumbar multifidus in the asymptomatic group. Again, the significant weaker lumbar extension strength in the LBP patients may be explained as dysfunction due to neuromuscular denervation of m. lumbar multifidus in the LBP group.[4,25,28] Therefore, the PAB® test appears to be reliable and valid by differentiating between the low back strength levels of LBP versus asymptomatic subjects ($p < .01$).

In conclusion, the international standard measurement tool for assessing muscle activation is kinesiological EMG.[29,30] Therefore, the significant correlation between EMG (μV) and PAB® force (mb) in m. lumbar multifidus contraction in this study indicated that the PAB® device may be recommended for measuring the back extension strength contraction of the lower lumbar spine in the upright seated, closed chain PAB® test. The results of the PAB® test differentiated between LBP and asymptomatic subjects lower lumbar extension strength, without any risk to the subject. Therefore, the PAB® device proves to be reliable and may be useful as a clinical testing instrument in the assessment of isometric extensor strength of the lower lumbar spine.

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Disclosure statement

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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