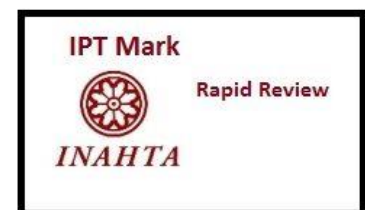




INFORMATION BRIEF (RAPID REVIEW)

DIGITAL HANDHELD DYNAMOMETER MUSCLE TESTER

**Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
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TITLE: DIGITAL HANDHELD DYNAMOMETER MUSCLE TESTER

PURPOSE

This review was conducted upon request by the Head of Physiotherapy Profession, Allied Health Sciences Division to provide information on the effectiveness, safety and cost-effectiveness of digital handheld dynamometer muscle tester following the interest to introduce this device in their services.

BACKGROUND

The assessment of muscle force output is a crucial clinical concern for patients with neurological, muscular and/or skeletal disorders. Clinicians can identify any restrictions and measure the growth of muscle strength over time based on accurate quantification of muscle force production by the application of muscle tester or dynamometer within clinical settings.¹ Examples of muscle parts that are commonly tested are shoulder abductors, elbow flexors, elbow extensors, wrist extensors, finger flexors, hand intrinsics, hip flexor, knee extensors, dorsiflexors, great toe extensor and plantar flexors.²

A dynamometer is a device that measures the effects of exercise on muscle strength. Examples of these devices include handgrips, which can be adjusted to test strength in various grasp positions, and bicycles, which record the muscular, respiratory, and metabolic effects of exercise directly from a pressure gauge (also known as an ergometer).³ There are types of devices / procedure used to measure the muscle strength, such as isokinetic dynamometer, manual muscle tester (MMT) and handheld dynamometer (HHD)⁴; for examples:



Figure 1: Example of Handheld Dynamometer



Figure 2: Example of Digital Handheld Dynamometer



Figure 3: Example of isokinetic dynamometer

The manual muscle test (MMT) is a common method used for more than a century in which the examiner will exert manual force with the patient moves their limbs against the gravity which then the strength will be evaluated and graded based on grading schemes.^{5, 6} The most common grading scheme is based on The Medical Research Council Manual Muscle Testing.^{2, 6} It relies on the examiner's perception, skills and experiences in order to rate the strength.^{2, 6} Although it does not require significant cost to operate, it has limited sensitivity to detect slight weakness and at times it overestimates the rate of strength by 25%.^{5, 6} As a result, MMT is practical in measuring significant decreased muscle function.

Isokinetic dynamometer is a golden standard used in measuring the muscle strength.¹ It is a technique that uses maximum torque production at a predetermined limb movement velocity to test and exercise extremities.⁶ It is an electromechanical tool used to measure the muscle torque at a certain movement speed and over the whole joint range.⁷ The dynamometer unit consists of a revolving arm with a speed-controlling mechanism and related data gathering, analysis, and display apparatus controlled by a microprocessor. The device may be positioned next to a chair or bench thanks to specialised attachments, which assess muscle performance across a variety of ankle, knee, hip, back, shoulder, and elbow movements as per Figure 3.⁷ It may provide better detection significant strength loss and assessing the muscle strength objectively compared to MMT and HHD.^{6, 8} Despite that, it may not be practical as it is costly and required a large space to place the whole equipment arrangement.^{6, 8}

The handheld dynamometer (HHD) is a small recording device hold by an examiner against patient's limb and the counter force measured then can be recorded by either analogue or digital output of HHD. The interval data recorded is measured in pounds, Newton or kilogram. Similar to MMT, HHD depends on both of examiners and patient's strength. In any situation, provided that the force by the examiner exceeded the patient's, the data obtained reflects the examiner's strength, rather than the patient. As a result, accurate data for weak patients could not be ascertained.^{4, 9}

EVIDENCE SUMMARY

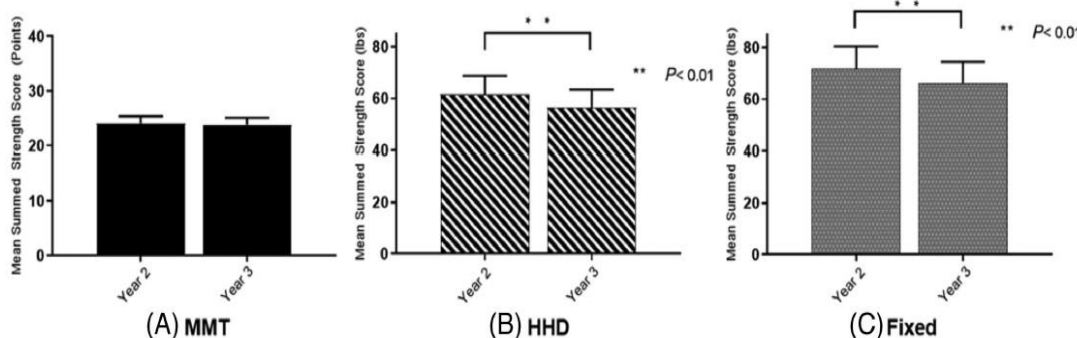
The systematic search found **four** relevant articles (one systematic review, one cohort and two cross sectional studies) related to digital dynamometer muscle tester from the scientific databases such as Medline, EBM Reviews via OVID, PubMed and from general search engines up to 15 December 2023 using the following search terms: *muscle strength / exercise therapy / muscle skeletal / hand strength*.

EFFICACY/ EFFECTIVENESS

A systematic review by Stark T et al (2011) involving 19 studies compared reliability and validity of the handheld dynamometer (HHD) against the gold standard for the assessment of the muscle strength i.e. isokinetic dynamometer from year 1988 to 2006. The review reported that the statistical outcomes demonstrating a noteworthy degree of validity and reliability between HHD and isokinetic muscle strength tests with 13 studies reported positive Pearson value (r) and two studies reported good intraclass correlation coefficient (ICC). The positive r value indicated a direct correlation between HHD and isokinetic dynamometer. In general, these studies concluded that HHD provided a moderate-to-good reliability and validity in comparison with isokinetic dynamometer. Other than that, HHD costs less and practical than isokinetic dynamometer, which requires a substantial area within the clinical settings.⁹

A cohort study by Reash et al (2022) involving 197 patients with dysferlinopathy across 15 sites in eight countries comparing the convergent validity and responsiveness to change of three testing modalities, i.e. manual muscle testing (MMT), handheld dynamometer (HHD) and fixed systems. The study found that at the end of year 2, all three modalities showed a high and significant correlation ($\rho > 0.8$, $P < 0.001$). However, after year 2, HHD and fixed frame system showed a significant decline in summed strength with median of decline at 2.8 and 5.3 pounds respectively, whereas MMT did not show significant changes throughout the duration as per Figure 4. It was pointed out that small improvement or decline in strength could not be detected by MMT scale, hence reducing its sensitivity. It was highlighted in the study that while most studies reported HHD have good to excellent ICCs when it is evaluated within a group at each point of time, it does not provide similar outcome with individual performance. In the test-retest reliability between screening and baseline visits, all muscle groups tested showed excellent ICCs for both HHD (0.82 – 0.96) and fixed system (0.81 - 0.96), however, it produced broad range of variability depending on type of muscles.¹⁰

Figure 4: Mean summed strength score of the cohort for all modalities at year 2 and 3^{10, 11}



A cross sectional study by González-Rosalén et al (2021) evaluated the intra- and inter-reliability for pull HHD and compared the inter-rater reliability of the pull HHD against the common method for the muscle strength measurement, i.e. push HHD. There were 40 healthy subjects in Spain with the range of age between 18 and 40 years old. In this experiment, the isometric tests were conducted by two trained sports and health professional of different body composition. The tests were conducted for both lower (hip, ankle) and upper limb (elbow and shoulder). They found that the ICCs for intra-session reliability was between 0.996 – 0.998 with standard error of management (SEM) values of less than 1%. On the other hand, the ICCs of the inter-rater reliability has shown excellent reliability of more than 0.991 with SEM lower than 1%. Both HHDs showed difference between raters of lower than 20N which ranged between 0.20% - 0.89% for pull HHD and push HHD at between 0.26% - 1.59% for some of the participants' measurements as illustrated in Table 1 for pull HHD and Table 2 for push HHD. For strength values greater than 200N, it was concluded that pull HHD maintained its disparity between raters while push HHD increased gradually.¹²

Table 1: Pull HHD inter-rater reliability and agreement by movement⁴

Isometric Test		Rater 1 (Male) Mean (SD)	Rater 2 (Female) Mean (SD)	ICC (95% CI)	SEM (%SEM)	Rater Differences (Rater 2 Minus Rater 1) Mean (%)	SD Difference Mean (%)
Hip	Flexion	351.92 (125.58)	339.22 (118.2)	0.992 (0.985 to 0.996)	1.95 (0.58%)	-12.70 (-3.61%)	21.82 (6.2%)
	Extension	210.28 (70.26)	208.84 (73.85)	0.991 (0.984 to 0.996)	1.26 (0.60%)	-1.44 (-0.69%)	13.24 (6.3%)
	Abduction	130.23 (26.94)	127.76 (26.16)	0.995 (0.991 to 0.998)	0.26 (0.20%)	-2.47 (-1.9%)	3.61 (2.77%)
	Adduction	145.33 (45.71)	142.34 (43.1)	0.998 (0.995 to 0.999)	0.19 (0.14%)	-2.99 (-2.06%)	4.36 (3%)
	IN rotation	115.68 (34.1)	113.19 (33.29)	0.995 (0.991 to 0.997)	0.33 (0.30%)	-2.49 (-2.15%)	4.73 (4.09%)
	EX rotation	129.62 (39.51)	127.53 (39.15)	0.998 (0.996 to 0.999)	1.13 (0.89%)	-2.08 (-1.61%)	3.57 (2.75%)
Ankle	Flexion	307.38 (130.95)	295.75 (123.9)	0.995 (0.991 to 0.998)	1.22 (0.41%)	-11.63 (-3.78%)	17.21 (5.6%)
	Extension	256.23 (116.67)	249.11 (113.42)	0.997 (0.995 to 0.999)	0.66 (0.26%)	-7.11 (-2.78%)	11.97 (4.67%)
Shoulder	Flexion	213.75 (87.17)	206.96 (83.27)	0.996 (0.993 to 0.998)	0.65 (0.31%)	-6.79 (-3.18%)	10.25 (4.79%)
	Extension	298.43 (141.48)	289.95 (132.62)	0.996 (0.993 to 0.998)	1.09 (0.37%)	-8.48 (-2.84%)	17.18 (5.76%)
	Abduction	106.83 (40.49)	104.96 (39.64)	0.999 (0.998 to 1)	0.07 (0.07%)	-1.87 (-1.75%)	2.31 (2.16%)
	IN rotation	139.37 (45.6)	139.03 (50.25)	0.999 (0.998 to 1)	0.09 (0.06%)	-2.79 (-1.97%)	2.86 (2.01%)
	EX rotation	141.82 (50.14)	136.53 (44.59)	0.997 (0.995 to 0.999)	0.25 (0.19%)	-2.84 (-2.04%)	4.63 (3.32%)
Elbow	Flexion	219.91 (112.98)	213.06 (106.79)	0.998 (0.996 to 0.999)	0.46 (0.22%)	-6.85 (-3.12%)	10.36 (4.71%)
	Extension	161.62 (68.68)	158.61 (67.36)	0.999 (0.998 to 1)	0.13 (0.08%)	-3.02 (-1.87%)	4 (2.47%)

SD = standard deviation; ICC = intra-class correlation; CI = confidence interval; SEM = standard error of measurement; IN = Internal; EX = External.

Table 2: Push HHD inter-rater reliability and agreement by movement¹³

Isometric Test		Rater 1 (Male) Mean (SD)	Rater 2 (Female) Mean (SD)	ICC (95% CI)	SEM (%SEM)	Rater Differences (Rater 2 Minus Rater 1) Mean (%)	SD Difference Mean (%)
Hip	Flexion	337.38 (114.98)	304.74 (110.26)	0.979 (0.96 to 0.989)	4.72 (1.55%)	-32.64 (-9.68%)	32.57 (9.65%)
	Extension	203.01 (67.13)	195.45 (74.97)	0.966 (0.935 to 0.982)	4.77 (2.44%)	-7.56 (-3.72%)	25.87 (12.74%)
	Abduction	128.24 (25.14)	120.92 (24.19)	0.976 (0.955 to 0.987)	1.17 (0.97%)	-7.32 (-5.71%)	7.54 (5.88%)
	Adduction	142.61 (43.17)	134.92 (41.84)	0.996 (0.992 to 0.998)	0.35 (0.26%)	-7.69 (-5.39%)	5.55 (3.89%)
	IN rotation	115.80 (33.81)	110.55 (32.75)	0.989 (0.980 to 0.994)	0.72 (0.65%)	-5.24 (-4.53%)	6.84 (5.91%)
	EX rotation	128.79 (38.69)	122.69 (36.54)	0.991 (0.983 to 0.995)	1.95 (1.59%)	-6.10 (-4.74%)	7.15 (5.55%)
Ankle	Flexion	289.92 (114.83)	252.50 (103.33)	0.978 (0.943 to 0.984)	6.48 (2.57%)	-37.43 (-12.91%)	37.40 (12.90%)
	Extension	248.60 (106.19)	228.64 (103.26)	0.987 (0.975 to 0.993)	2.75 (1.20%)	-19.97 (-8.03%)	24.08 (9.69%)
Shoulder	Flexion	201.07 (79.36)	183.95 (70.6)	0.985 (0.971 to 0.992)	2.25 (1.22%)	-17.11 (-8.51%)	18.37 (9.14%)
	Extension	278.45 (124.56)	251.41 (107.06)	0.964 (0.933 to 0.981)	8.18 (3.25%)	-27.04 (-9.71%)	43.09 (15.47%)
	Abduction	103.24 (37.35)	97.82 (35.53)	0.996 (0.992 to 0.998)	0.30 (0.30%)	-5.42 (-5.25%)	4.72 (4.57%)
	IN rotation	139.51 (48.38)	132.03 (47.82)	0.991 (0.983 to 0.994)	0.43 (0.33%)	-7.48 (-5.36%)	4.49 (3.22%)
	EX rotation	136.70 (43.78)	130.50 (39.61)	0.998 (0.996 to 0.999)	0.35 (0.27%)	-6.20 (-4.53%)	7.92 (5.79%)
Elbow	Flexion	207.87 (99.62)	189.79 (89.26)	0.989 (0.979 to 0.994)	2.09 (1.10%)	-18.09 (-8.70%)	19.91 (9.58%)
	Extension	156.50 (65.6)	148.00 (64.08)	0.997 (0.995 to 0.998)	0.38 (0.26%)	-8.49 (-5.43%)	6.93 (4.43%)

SD = standard deviation; ICC = intra-class correlation; CI = confidence interval; SEM = standard error of measurement; IN = Internal; EX = External.

A cross sectional study by Bairapareddy et al (2023) comparing the reliability and concurrent validity to measure the isometric handgrip strength between [redacted] digital dynamometer and the traditional [redacted] dynamometer, and analysing the connection between hand measures, anthropometric measurements, and the resting blood pressure and handgrip strength between two modalities. There were 30 participants involved in the study. The results reported that both modalities have excellent intra-rater reliability coefficients of more than 0.99 for three testers. The ICC were reported at 0.93 and 0.87 (p=0.001) for [redacted] and [redacted] respectively. The ICC between [redacted] dynamometer was 0.844 with r-value of 0.72 (p=0.001) indicating both are valid and statistically significant in determining the handgrip strength. Based on Bland Altman plot between the modalities measurement were determined to be -7.04 and 12.84 for [redacted], respectively, which indicated a valid agreement between both indicated high reliability.¹⁴

SAFETY

As of today, there was no technology registered related to the digital dynamometer muscle tester with the Malaysian Medical Device Authority (MDA). Non-powered and AC-powered dynamometer are exempted from pre-market notification requirements under the Food and Drug Administration Modernization Act of 1997 (FDAMA) or the 21st Century Cures Act of 2016 (Cures Act), United States Food and Drug Administration (US FDA).¹⁵

COST-EFFECTIVENESS

Stark et al (2011) highlighted that the initial expenses for HHD and isokinetic testing equipment varies significantly; an HHD can cost about USD1,000, while a [REDACTED] isokinetic device can cost up to USD40,000.⁹ Later in 2022, Reash et al compared that there was no additional cost applied to MMT, however approximately USD1,200 is required for the standardised equipment for HHD and USD20,000 is required for the fixed systems.¹⁰ The local price as quoted locally for several brands of dynamometer that comes with its software are between RM15,000 – 28,000 per unit.

CONCLUSION

Based on the review, there were limited evidence on HHD which showed that it has good ICC comparable to the fixed system. However, it has wide variability in terms of individual performance. Pull HHD was also shown to provide good reliability and concordance between measurements recorded by examiners with different body and strength profile. [REDACTED] digital dynamometer also provided high reliability similar to [REDACTED] handheld dynamometer. These modalities are exempted from pre-market notification under USFDA and however currently not listed under MDA.

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