TECHNOLOGY REVIEW (MINI-HTA)

DIGITAL GONIOMETER

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
011/2023

IPT Mark
Mini-HTA
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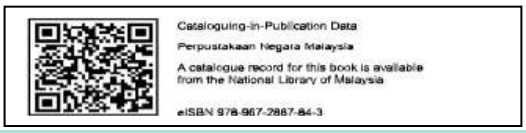
EVIDENCE INFORMED DELIBERATIVE PROCESS

This Technology Review underwent evidence informed deliberative process during the Health Technology Assessment (HTA) Technical Advisory Committee meeting, chaired by the Director, Medical Development Division, MOH. Then it was endorsed in the HTA-CPG Council meeting chaired by the Director General of Health.

Published by:
Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
Level 4, Block E1, Precinct 1
Government Office Complex
62590, Putrajaya
Tel: 603 8883 1229
Available online via the official Ministry of Health Malaysia website: http://www.moh.gov.my
eISBN: 978-967-2887-84-3


Cataloguing-in-Publication Data
Perpustakaan Negara Malaysia
A catalogue record for this book is available from the National Library of Malaysia
eISBN 978-967-2887-84-3

SUGGESTED CITATION: Nurul Nashriq MH, Roza S and Izzuna MMG. Digital Goniometer. Technology Review. Ministry of Health Malaysia: Malaysian Health Technology Assessment Section (MaHTAS); 2024. 33 p. Report No.: 011/2023

DISCLOSURE: The author of this report has no competing interest in this subject and the preparation of this report is entirely funded by the Ministry of Health Malaysia.

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EXECUTIVE SUMMARY

Background

Range of motion (ROM) is defined as the measurement of movement around a particular joint or body component, which can be a technique or as an assessment tool. Restrictions in ROM can result from traumas like bone fractures or neurological illnesses like stroke. Physicians and physical therapists measure joint ROM for diagnosis, disease severity evaluation, and prognosis prediction.

ROM can be measured using a variety of equipment, including goniometers (universal and joint specific), inclinometers, tape measures, electrogoniometers, photography, video recording, and radiography. A goniometer is an instrument that can spin an object to a certain position or measure an angle. There are several varieties of goniometers utilised, including universal goniometers, digital goniometers, twin axis electrogoniometers, arthrodial goniometers, and gravity goniometers/inclinometers and smartphone goniometry application. According to Malaysian Medical Device Authority (MDA), goniometer / inclinometer /scoliometer are defined as 'posture evaluation instruments provide accurate and repeatable measurements.' There is strong interest in digital goniometer as it is easy to use, convenient, portable and minimum training required. [1, 2] There is strong interest in digital goniometer as it is easy to use, convenient and portable. [1] Majority healthcare facilities in Malaysia are using universal goniometer in measuring ROM.

The relative reliability and validity of the goniometer are often measured by intra-class correlation (ICC), concordance correlation coefficient (CCC) and Pearson's product momen correlation (r). On the other hand, the absolute reliability and validity measured based on standard error of measurement (SEM), minimal detectable change (MDC), mean difference (MD) and limits of agreement (LOA).

Objective/ aim

The objective of this technology review was to assess the effectiveness, safety, and economic implication of digital goniometer.

Results and conclusions:

Search results

A total of 11 records were identified through the Ovid interface and PubMed, and 51 records identified from other websites. Seven duplicates' references were found; 55 potentially relevant titles were screened using the inclusion and exclusion criteria. Of these, 40 relevant abstract was retrieved in full text. After reading, appraising and applying the inclusion and exclusion criteria to the 40 full text articles, 9 were included. Those were excluded as those primary studies were already included in systematic review (n=5), irrelevant study design (n=4), not relevant to DG (n=10), review articles (n=2) and funding bias (n=1). A total of nine full text articles were finally included in this review comprised of one systematic review, one prospective cohort study and seven cross-sectional studies.

Effectiveness

In general, evidence demonstrated that most of the studies identified that digital goniometer or smartphone goniometry application demonstrated between good to excellent inter- and intra-rater reliability with other types of goniometers for variety of joints studied. Evidence demonstrated that the device has good validity against other types of goniometers.

Safety

There was no study retrieved related to the safety of the digital goniometer or smartphone goniometry application. Malaysian Medical Device Authority (MDA) requires the registration of goniometer for Malaysian market. US FDA classified goniometer as Class I and Class II device which are exempted from the pre-market notification.

Organisational:

With sufficient training and familiarisation, handling of goniometer can be handled by new assessor.

Economic implication

There was no evidence retrieved on the cost-effectiveness or other economic analysis related to digital goniometer or smartphone goniometry application. The estimated price for [redacted] digital goniometer is [redacted] and the smartphone goniometry application can be in between the range of free to [redacted] per application.

Conclusion

Universal goniometer, digital goniometer and smartphone goniometry application demonstrated good to excellent performance for measuring joint ROM except for cervical joint. No safety issue reported and no major economic implication.

Methods

Electronic databases were searched through the Ovid interface: Ovid MEDLINE and EBM Reviews - Cochrane Database of Systematic Reviews 2005 to 19th January 2024, EBM Reviews - Cochrane Central Registered of Controlled Trials January 2023, EBM Reviews - Database of Abstracts of Review of Effects 1st Quarter 2016, EBM Reviews - NHS Economic Evaluation Database 1st Quarter 2016. PubMed, US FDA, INAHTA and general database such as Google Scholar were used to search for additional web-based materials and information. Additional articles retrieved from reviewing the bibliographies of retrieved articles. The search was limited to articles on human. There was no language limitation in the search. The last search was conducted on 18th March 2024.

TABLE OF CONTENTS

ABBREVIATION

AAROM	Active-assisted range of motion
AEs	Adverse events or adverse effects
AROM	Active range of motion
CASP	Critical Appraisal Skills Programme
CCC	Concordance correlation coefficient
CI	Confidence interval
CPM	Continuous Passive Motion
DG	Digital Goniometer
FRT	Flexion-rotation-test
ICC	Intra-class correlation coefficient
INAHTA	International Network of Agencies for Health Technology Assessment
LOA	Limits of agreement
MaHTAS	Malaysian Health Technology Assessment Section
MD	Mean difference
MDA	Medical Device Authority
MDC	Minimal detectable change
MOH	Ministry of Health
PROM	Passive range of motion
r	Pearson's product moment correlation
RCT	Randomised controlled trial
RD	Risk difference
RoB	Cochrane Risk of Bias Tool
ROBIS	National Collaborating Centre for Methods and Tools
ROM	Range of motion
SEM	Standard error of measurement
SGR	Smartphone goniometer record application
SRD	Smallest Range Difference
UG	Universal Goniometer
US FDA	United States Food and Drug Administration

1.0 BACKGROUND

Range of motion (ROM) is defined as the measurement of movement around a particular joint or body component, which can be a technique or as an assessment tool. [3, 4] Restrictions in range of motion (ROM) can result from traumas like bone fractures or neurological illnesses like stroke. [5] These restrictions can hinder daily tasks like walking. Physicians and physical therapists measure joint range of motion (ROM) for diagnosis, disease severity evaluation, and prognosis prediction. [5]

There were three types of ROM depending on the purpose of the assessment; i.e. passive ROM, active ROM and active assistive ROM. Passive ROM (PROM) is the ROM obtained when an outside force (such as a therapist or a CPM machine) only produces movement of a joint, and it is typically the maximum range of motion that a joint can move. Usually done when the patient is incapable or not allowed to move a body part. Meanwhile, active range of motion (AROM) is the amount of ROM that may be achieved by contracting and relaxing opposing muscles, resulting in joint movement. For example, the active range of motion to bend the elbow requires the biceps to flex while the triceps relaxes. Active range of motion is often shorter than passive range of motion. When a patient is able to deliberately contract, control, and coordinate a movement, they can usually perform it on their own. Besides that, active-assisted range of motion (AAROM) occurs when the joint receives partial support from an external force. Typically used when the patient need aid with movement from an external stimulus due to weakness, pain, or changes in muscle tone. [6]

ROM can be measured using a variety of equipment, including goniometers (universal and joint-specific), inclinometers, tape measures, electrogoniometers, photography, video recording, and radiography.[3] A goniometer is an instrument that can spin an object to a certain position or measure an angle.[1] It is derived from two Greek words: gonia (angle) and metron (to measure).[1] There are several varieties of goniometers utilised, including universal goniometers, digital goniometers, twin axis electrogoniometers, arthrodial goniometers, and gravity goniometers/inclinometers and smartphone goniometry application. [3] According to MDA, goniometer / inclinometer / scoliometer are defined as ‘posture evaluation instruments provide accurate and repeatable measurements’. [7] There is strong interest in digital goniometer as it is easy to use, convenient and portable. [1] Majority in healthcare facilities in Malaysia are using universal goniometer in measuring ROM.

The relative reliability and validity of the goniometer are often measured by intra-class correlation (ICC), concordance correlation coefficient (CCC) and Pearson’s product moment correlation (r). On the other hand, the absolute reliability and validity are measured based on standard error of measurement (SEM), minimal detectable change (MDC), mean difference (MD) and limits of agreement (LOA). [8]

Both Hancock et al. (2018) and Keogh et al. (2019) reported the disadvantages of using smartphone applications to measure goniometers due to the smartphone application's quick development in terms of both software and hardware. [8, 9] This technology review was requested by the Head of Profession for Physiotherapist from Hospital Sultanah Aminah,

Johor to evaluate the reliability and validity of the digital goniometer against the standard measurement device such as universal goniometer.

2.0 OBJECTIVE / AIM

The objective of this technology review was to assess the effectiveness, safety, and economic implication of digital goniometer.

3.0 TECHNICAL FEATURE

There are a number of technical aspects need to be considered / suggested in assessing the ROM by using the goniometer, [10] among which;

i. Positioning of patient is consistent with a well-defined testing positions and anatomical landmarks in order to align the arms of the goniometer,
ii. The same type goniometer is used for daily repeated measurement for the same patient
iii. Measure ROM using a standardised protocol/procedure
iv. Use suitable goniometer for different measuring joints
v. One reading is sufficient for an experienced examiner. However, it is advisable the average of several measurements should be considered for inexperienced examiners.

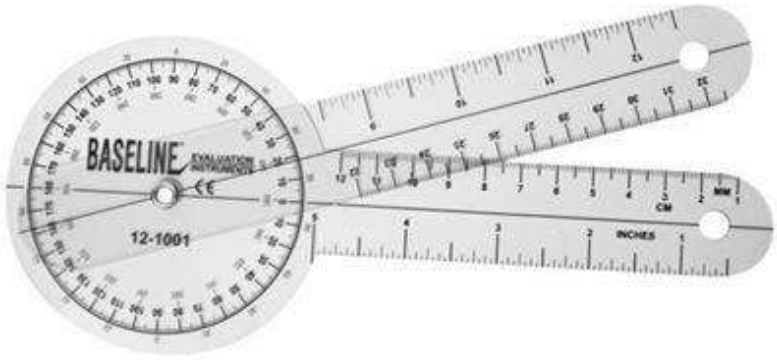

Figure 1: Universal Goniometer

The universal goniometer is the most commonly used goniometer. It has two forms – short and long arm[3]. The short arm is used for smaller joints such as wrist, elbow, ankle and the long arm is used for joints with long levers such as knee and hip joints.

Figure 2: Digital goniometer[11]

This digital goniometer can work both as goniometer and inclinometer. It can be handled single handedly and pocket size. It emits lasers to intersect the anatomical landmark for repeating measurements.

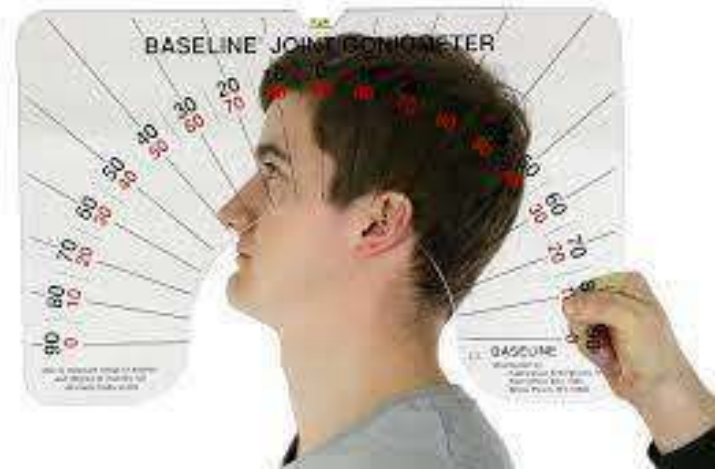

Figure 3: Arthrodial goniometer

The arthrodial goniometer is an ideal device to measure cervical rotation, anteroposterior flexion, lateral flexion of the cervical spine.[3]

Figure 4: Twin axis electrogoniometer

The twin axis electrogoniometer, on the other hand, is often used for the purpose of research. [3]

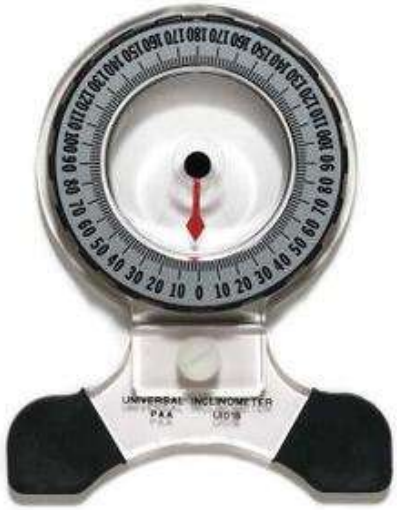

Figure 5: Inclinometer

The inclinometer contains a sensor that is sensitive to the gravity in which the angle of the sensor will move according to the movement of the joint.

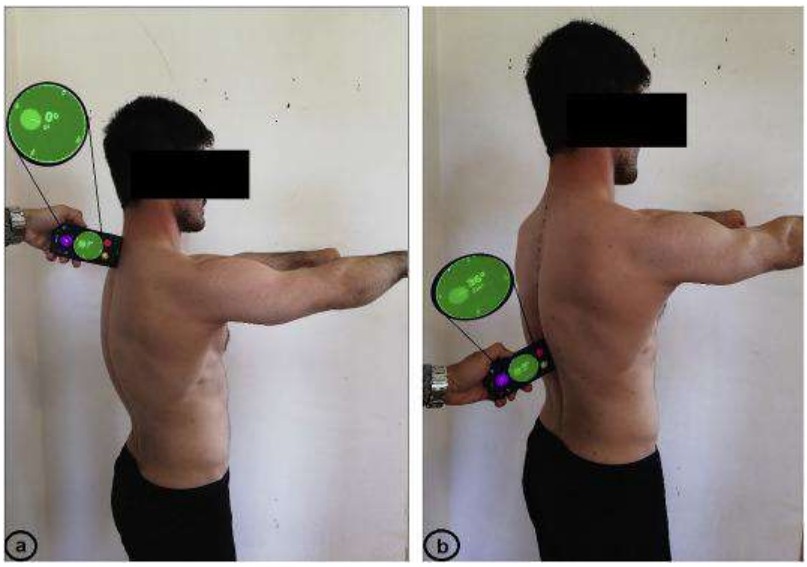

Figure 6: Smartphone based application goniometer

It uses internal accelerometers as the position sensor, as well as the other application that is positional dependent[12, 13]

According to Keogh (2019) and Alawna (2019), the interpretation of the measurements of the reliability and validity are as follows; [8, 14]

Table 1: Measurements of reliability and validity

Relative Measures		
ICC	CCC	r
Excellent ≥ 0.75 Good = ICC 0.60 – 0.74 Fair = ICC 0.40 – 0.59 Poor = ICC < 0.40	Almost perfect CCC > 0.99 Substantial CCC = 0.95 – 0.99 Moderate CCC = 0.90 – 0.94 Poor CCC < 0.90	Very high r = 0.90 – 1.00 High r = 0.70 – 0.89 Moderate r = 0.50 – 0.69 Low r = 0.30 – 0.49 Negligible = 0 – 0.29
Absolute Measures		
SEM	MDC	LOA
Good SEM ≤ 5º Poor SEM > 5º	Good MDC ≤ 5º Poor MDC > 5º	Standard deviation threshold of 5º then multiplied by 1.96 to derive the 95% LOA bandwidth; Good < ± 9.8º Poor > ± 9.8º

4.0 METHODS

A systematic review was conducted. Search strategy was developed by the main author and an *Information Specialist*.

4.1 SEARCHING

The following electronic databases were searched through the Ovid interface:

- MEDLINE® All < 1946 to 19th January 2024>
- EBM Reviews - Health Technology Assessment 4th Quarter 2016
- EBM Reviews - Cochrane Database of Systematic Reviews 2005 to 19th January 2024
- EBM Reviews - Cochrane Central Registered of Controlled Trials January 2023
- EBM Reviews - Database of Abstracts of Review of Effects 1st Quarter 2016
- EBM Reviews - NHS Economic Evaluation Database 1st Quarter 2016

Other databases: PubMed, US FDA, INAHTA

General databases such as Google Scholar was used to search for additional web-based materials and information. Additional articles retrieved from reviewing the bibliographies of retrieved articles. The search was limited to articles on human. There was no language limitation in the search. **Appendix 1** showed the detailed search strategies. The last search was conducted on 18th March 2024.

4.2 SELECTION

A reviewer screened the titles and abstracts against the inclusion and exclusion criteria. Relevant articles were then critically appraised depending on the type of the study design. Studies were graded according to *US/ Canadian Preventive Services Task Force* (**Appendix 2**). All data were extracted and summarised in evidence table as in **Appendix 3**.

The inclusion and exclusion criteria were:

Inclusion criteria:

a.	**Population**	Patient with rehabilitation, healthy participants
b.	**Intervention**	Digital goniometer, Smartphone based application goniometer

c.	**Comparator**	1 – Universal goniometer 2 – Twin Axis Electrogoniometer 3 – Gravity Goniometer / Inclinometer 4 – Athrodial goniometer
d.	**Outcomes**	**Effectiveness:** Accuracy in quantifying ROM of specific joint or body part **Safety:** Adverse events (AEs) related to use of the device **Organisational issues:** training or learning curve **Economic implications:** Cost, cost-effectiveness, cost-utility analysis
e.	**Study design**	HTA reports, systematic review with/out meta-analysis, randomised controlled trial (RCT), cohort, diagnostic, case-control, economic evaluation studies
f.	Full text articles published in English	

Exclusion criteria:

a.	**Study design**	Case report, case series, animal study, laboratory study, narrative review
b.	Non-English full text articles	

5.0 RESULTS

Search results

An overview of the search is illustrated in **Figure 7**. A total of 11 records were identified through the Ovid interface and PubMed, and 51 records identified from other websites. Seven duplicates' references were found; 55 potentially relevant titles were screened using the inclusion and exclusion criteria. Of these, 40 relevant abstract was retrieved in full text. After reading, appraising and applying the inclusion and exclusion criteria to the 40 full text articles, nine were included. Those were excluded as those primary studies were already included in systematic review (n=5), irrelevant study design (n=4), not relevant to DG (n=10), review articles (n=2) and insufficient outcome (n=2). All full text articles finally selected for this review comprised of one systematic review, one prospective cohort study and seven cross-sectional studies.

Summary of the included studies was as illustrated in the Table 2. Apart from one systematic review and cohort study, there were eight cross-sectional studies. These papers highlighted the ICC and validity aspects of the different types of goniometers. In total, there were 381 subjects involved in the cohort and cross-sectional studies from Australia, United States of America, Republic of Turkiye, Thailand, Austria, and Sweden.

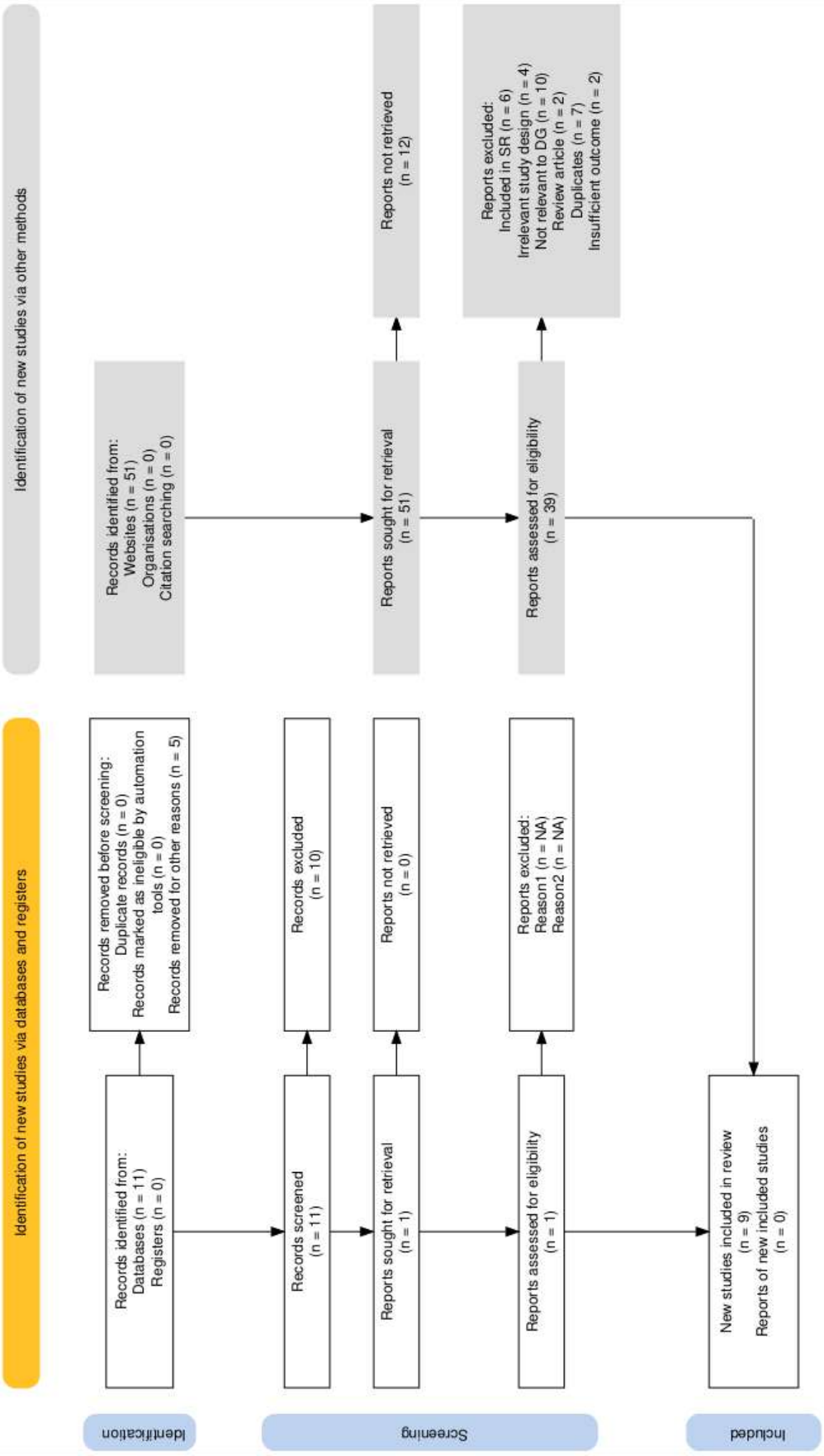

Figure 7: Flow chart of retrieval of articles used in the results[15]

Table 2: Description of included studies for the review

	Study	Study Design	Number of participants / patients	Intervention	Comparator	Outcome
1.	Keogh JWL et al. (2019) [8]	Systematic review	37 studies	Smartphone goniometry application	• Goniometer • 3D motion analysis • Inclinometer • Cervical Range of Motion (CROM)	• Intra-rater reliability (ICC) • Inter-rater reliability (ICC) • Validity SEM, MDC, LOA
2.	Wilson-Smith AR et al. (2022) [16]	Prospective cohort	100 healthy subjects from university in Australia	Digital goniometer	Universal goniometer	• Inter-rater reliability (ICC) • Intra-reliability (ICC) • MDC • Concurrent validity (MDC)
3.	Correll S et al. (2018) [17]	Cross sectional	41 healthy volunteers from University of California San Franscisco	HALO® digital goniometer	Universal goniometer	• Inter-rater reliability (ICC) • Intra-rater reliability (ICC) • SEM, SRD
4.	Alawna MA et al. (2019) [14]	Cross sectional	58 healthy participants	Universal goniometer	Smartphone Goniometer Record (SGR) application	• Inter-rater reliability (ICC) • Intra-rater reliability (ICC) • Bland Altman plot
5.	Kiatkulanusom S. et al (2023) [18]	Cross sectional	Ten healthy individuals	Universal goniometer, inclinometer, digital inclinometer, smartphone application, modified inclinometer		• Intra-rater reliability (ICC) • Inter-rater reliability (ICC) • SEM, MDC, LOA

	Study	Study Design	Number of participants / patients	Intervention	Comparator	Outcome
6.	Luedtke K et al. (2020) [1]	Cross sectional	Reliability: 50 patients Validity: 62 patients	EasyAngle® goniometer	Zebris system (Ultrasound)	• Validity • Inter-rater reliability (ICC) • Intra-rater reliability (ICC) • SEM, LOA, Mean difference
7.	Duffy E et al. (2024) [19]	Cross sectional	Twenty healthy elementary school children	EasyAngle® digital goniometer	N/A	• Intra-rater reliability (ICC) • Inter-rater reliability (ICC)
8.	Koong DP et al. (2020) [20]	Cross sectional	Twenty paediatrics patients	Smartphone goniometer application	• Universal goniometer • Visual estimation	• Inter-rater reliability (ICC) • Intra-rater reliability (ICC) • LOA
9.	Svensson M et al. (2018) [21]	Cross sectional	Twenty healthy participants	EasyAngle® digital goniometer	N/A	• Intra-rater reliability (ICC) • Inter-rater reliability (ICC)

Quality assessment of the studies

The risk of bias or quality assessment (methodology quality) of all retrieved literatures was assessed depending on the type of the study design. These assessments involved answering a pre-specified question of those criteria assessed and assigning a judgement relating to the risk of bias: using the relevant checklist of National Collaborating Centre for Methods and Tools (ROBIS) [22] for systematic review and meta-analysis and Critical Appraisal Skill Programme (CASP) checklist for observational study. [23] All full text articles were graded based on guidelines from the *U.S. / Canadian Preventive Services Task Force*.[31]

Risk of bias assessment for included systematic review

The systematic review by Keogh JWL et al. (2019) was rated to have an overall high risk of bias. The review defined a clear clinical question with pre-defined objective including appropriate inclusion and exclusion criteria. However, there was no data synthesis conducted by the authors to identify any error in the data collection.

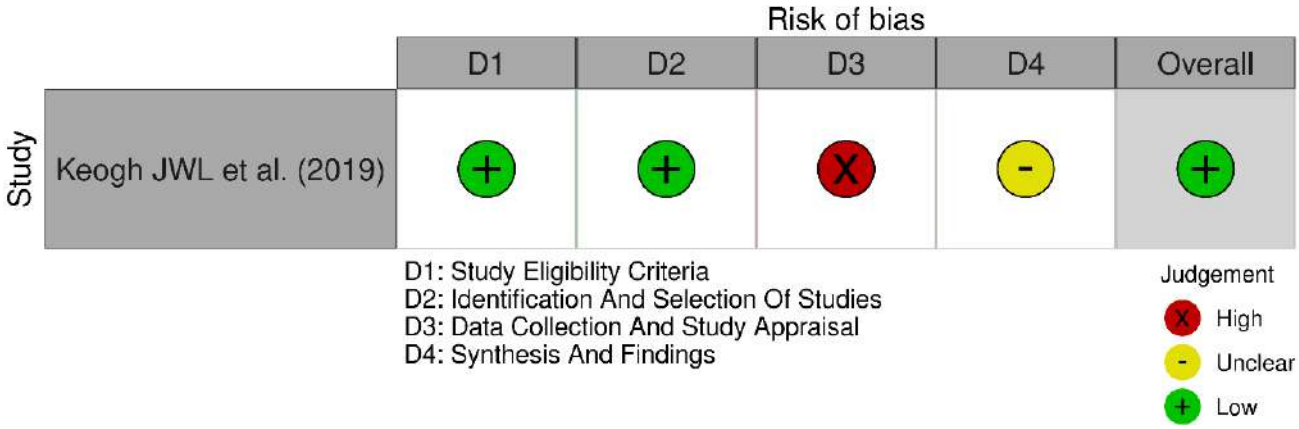

Figure 7.1: Risk of bias assessment for systematic review and meta-analysis using ROBIS

Risk of bias assessment for included cohort using CASP

Based on the CASP checklist, the study had low risk of bias.

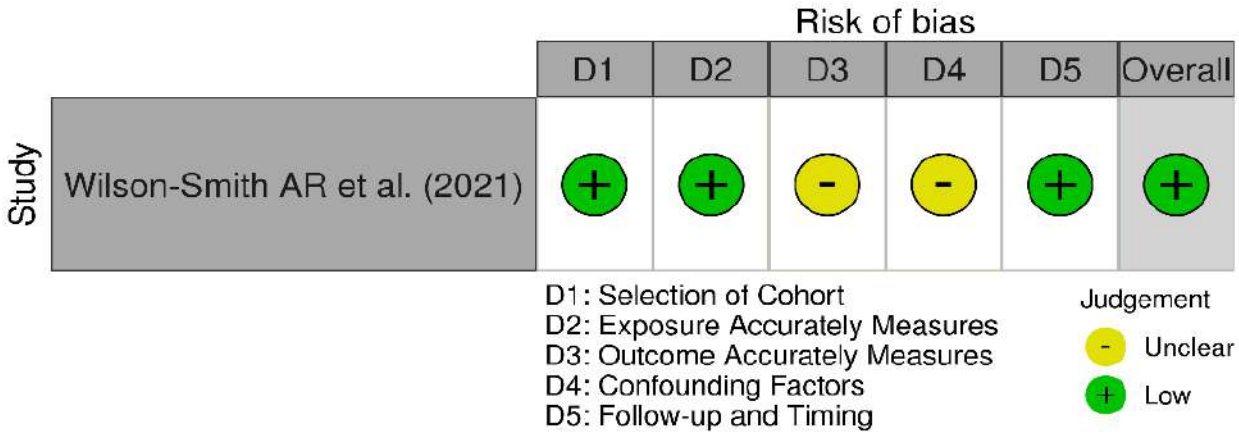

Figure 7.2: Risk of bias assessment for cohort study using CASP

5.1 EFFICACY/ EFFECTIVENESS

5.1.1 Smartphone Application

A systematic review by Keogh JWL et al. (2019) with 37 eligible studies under the objective to analyse in analysing the intra- and inter-rater reliability, as well as the validity of the smartphones and software in measuring the range of motion (ROM). Most of the studies included involved healthy participants, while some focused patients with conditions such as neck pain, knee pain, shoulder pathology or numerous upper limb injuries. The joints assessed were mostly spine / trunk, knee, shoulder, while some smaller studies covered wrist, elbow, ankle and hip joints. Majority of the paper (25 out of 26 studies) reported the intra-rater reliability as excellent ICC > 0.75 for 50% of the measurement of joints examined, meanwhile 13 out of 17 studies reported good absolute of SEM or MDC < 5º or LOA < ± 9.8º for 50% of the measurement of joints examined. Inter-rater reliability of 23 out of 25 studies reported excellent inter-rater reliability as well as six out of 11 studies reported good absolute of SEM or MDC < 5º or LOA < ± 9.8º for 50% of the measurement of joints examined. In terms of relative validity, 20 out of 25 studies reported excellent / substantial relative validity based on ICC > 0.75, r > 0.9 or CCC > 0.95 for 50% of the measurement of joints examined. Likewise, the absolute validity of 17 studies out of 23 reported excellent / substantial absolute validity based on SEM or MDC < 5º or LOA < ± 9.8º for 50% of the measurement of joints examined. The review stated that based on the assessment of absolute validity, it is recommended that clinicians use the same assessment modality for a patient at different time periods. [8 Level I]

5.1.2 Digital Goniometer (HALO®) vs. Universal Goniometer

A cohort study by Wilson-Smith AR et al. (2021) conducted on 100 healthy subjects in Australia with the objective to evaluate the validity, intra- and inter-rater validity of the cervical spine of the digital goniometer against the universal goniometer. The subjects were those aged more than 18 years old with no current cervical spine injuries known. There were two cohorts of assessors comprised of physiotherapists and medical students. Subjects were randomly grouped into four groups (two assessors per group). The average follow-up time was 31.3 days. The study involved cervical flexion, extension, lateral flexion and rotation. Within the physiotherapists' cohort, the inter-rater reliability for cervical extension was good with ICC of 0.819 for UG and 0.780 for DG. Meanwhile, UG had poor reliability for cervical flexion (ICC of 0.300) and rotation (ICC of 0.255), however modest reliability for DG with ICC of 0.477 and 0.551, respectively. On the other hand, in medical student cohort, UG showed modest reliability for all planes of motion. Meanwhile, DG showed the reliability between modest and good with range values of 0.477 and 0.831. Intra-rater reliability reported that within the physiotherapy cohort, the most accurate planes were cervical extension for the UG with MDC value of 9.7° and cervical lateral flexion for the DG with MDC value of 8.0°. The cervical lateral flexion for the UG and cervical flexion for DG were the most accurate with MDC90 values of 10.48 and 10.10 degrees, respectively. For the concurrent validity, the smallest mean difference observed between UG and DG when assessing the cervical lateral flexion by all raters, which later supported by Bland Altman plot as in Figure 8. In contrary, the cervical flexion showed statistically significant difference for every rater. [16 Level II-2]

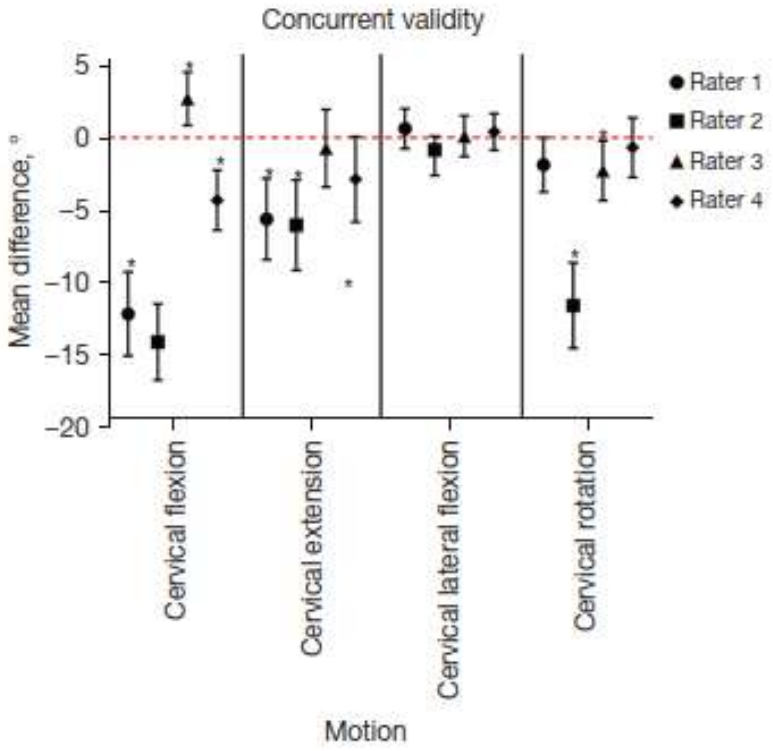

Figure 8: Mean difference of the measurements by each rater for every motion[24]

Correll S et al. (2018) in a cross-sectional study between HALO® digital goniometer and UG for the purpose to assess the intra- and inter-reliability, and concurrent validity of both modalities in measuring active shoulder ROM among 41 healthy volunteers from University of California San Francisco, USA. It involved four motions, i.e. active shoulder flexion, abduction, internal and external rotation. Out of 41 volunteers, 79 shoulders (39 right and 36 left sides) were measured. For intra-rater reliability, the ICC for HALO® ranged between 0.82 to 0.91 whereas the ICC for UG ranged between 0.83 to 0.95, concluded the ICC were within good and excellent, as per Table 2. The intra-rater SRD was similar for HALO® was 6.9 to 21.1º and for UG, it's 6.8 to 15.1º. The highest SRD reported for abduction by both raters using HALO® was 21.1º and 14.1º for Rater A and Rater B, respectively. In terms of inter-rater reliability between two devices was 0.89 to 0.98 for HALO® and 0.90 to 0.98 for UG. Standard Error of Measurement (SEM) and Smallest Range Difference (SRD) for HALO were higher than UG for flexion and abduction but similar for internal and external rotation as per Table 1. [17 Level III]

Table 3: Comparison between Rater A and Rater B for the intra-rater reliability of the shoulder ROM[25]

Movement (Rater)	Halo $ICC_{3,1}$ (95% CI)	Halo SEM	Halo SRD	Goniometer $ICC_{3,1}$ (95% CI)	Goniometer SEM	Goniometer SRD
Flexion (Rater A)	.86 (.77-.91)	2.7	7.5	.83 (.71-.90)	2.5	6.8
Flexion (Rater B)	.88 (.79-.92)	2.5	6.9	.84 (.75-.90)	2.8	7.7
Abduction (Rater A)	.86 (.77-.91)	7.6	21.1	.94 (.90-.96)	3.9	10.8
Abduction (Rater B)	.91 (.85-.94)	5.1	14.1	.95 (.92-.97)	3.5	9.8
IR (Rater A)	.82 (.71-.89)	5.7	15.9	.83 (.73-.89)	5.5	15.1
IR (Rater B)	.85 (.75-.90)	5.7	15.9	.87 (.78-.92)	5.2	14.3
ER (Rater A)	.90 (.84-.94)	4.2	11.7	.90 (.85-.94)	4.0	11.1
ER (Rater B)	.89 (.82-.93)	4.3	11.9	.88 (.81-.92)	4.2	11.7

CI: Confidence interval; ER: External Rotation; ICC: Intraclass correlation coefficient; IR: Internal Rotation; SEM: Standard Error of the Measurement; SRD: Smallest Real Difference

Table 4: Comparison between Rater A and Rater B for the inter-rater reliability of the shoulder ROM[26]

Movement	Halo $ICC_{3,2}$ (95% CI)	Halo SEM	Halo SRD	Goniometer $ICC_{3,2}$ (95% CI)	Goniometer SEM	Goniometer SRD
Flexion	.89 (.82-.93)	2.3	6.4	.90 (.80-.94)	1.9	5.3
Abduction	.93 (.88-.95)	4.7	13.0	.97 (.91-.99)	2.7	7.4
IR	.96 (.90-.98)	2.5	6.9	.96 (.92-.98)	2.6	7.1
ER	.98 (.96-.99)	1.8	4.9	.98 (.96-.99)	1.7	4.6

CI: Confidence interval; ER: External Rotation; ICC: Intraclass correlation coefficient; IR: Internal Rotation; SEM: Standard Error of the Measurement; SRD: Smallest Real Difference

5.1.3 Smartphone Goniometer Record (SGR) Application vs. Universal Goniometer

Alawna MA et al. (2019) in a diagnostic study conducted for 58 healthy participants (29 men and women between the age of 18 – 30 years old) for the purpose of assessing the reliability of the smartphone goniometer record (SGR) against universal goniometer (UG) for ankle joint by two examiners, as well as assessing the inter- and intra-reliability of SGR. In this study, the examiners were blinded during the measurement taking and the data derived from it were recorded by two independent recorders. The focus joint movements were ankle dorsiflexion and plantarflexion. In summary, both modalities possess excellent inter- and intra-reliability. For ankle dorsiflexion, inter-rater reliability of UG and SGR reported ICC of 0.87 and 0.89, respectively. On the other hand, the inter-rater reliability for ankle plantarflexion for UG was ICC 0.76, whilst SGR recorded ICC = 0.82. Meanwhile, the intra-rater reliability for both UG and SGR of ICC was 0.91. Furthermore, Figure 9 showed that SGR produced more consistent data compared to UG. As the mean ± SD ROM of ankle dorsiflexion was 19.24° ± 3.87°, whilst SGR was 20.34° ± 3.61°. On the other hand, mean ± SD ROM of ankle plantarflexion with UG was 53.28° ± 10.4°, whilst SGR 51.23° ± 4.95°, which signifies the correlation between UG and SGR was significant. [14] Level III

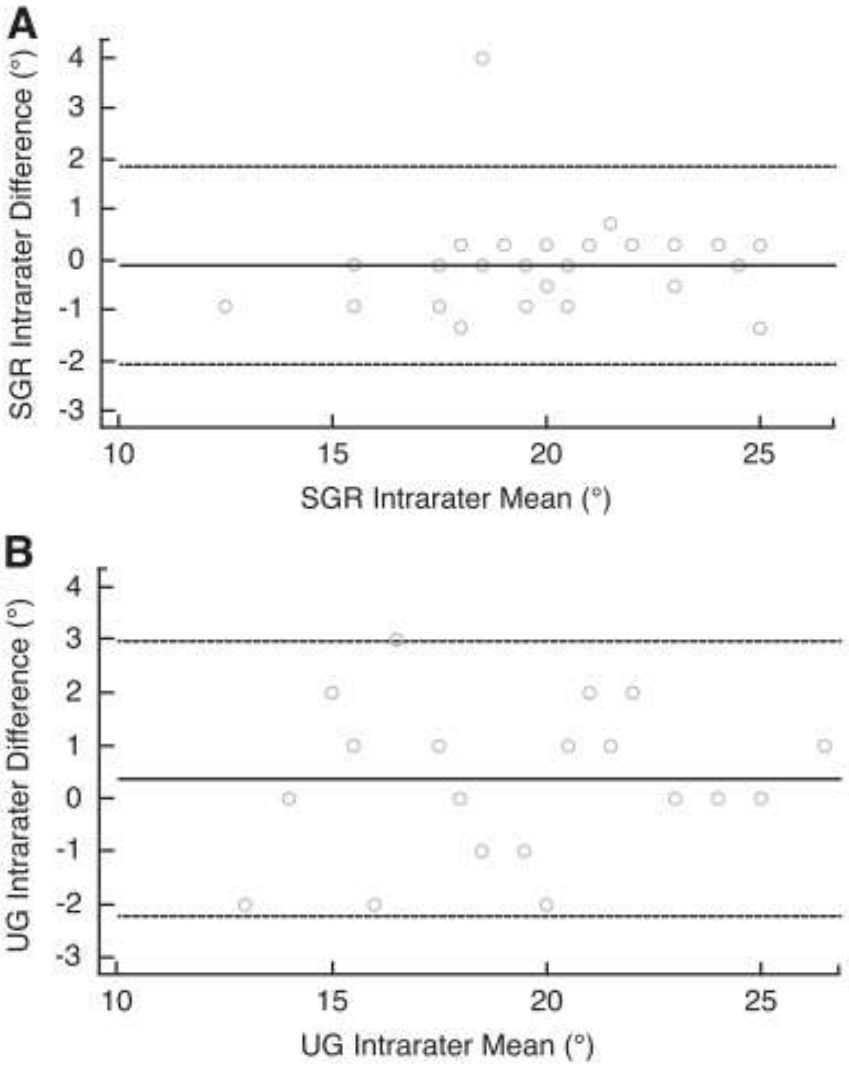

Figure 9: The Bland Altman plot on intra-rater reliability for UG and SGR[27]

5.1.4 Universal Goniometer (UG), Inclinometer (IC), Digital Inclinometer (DI), Smartphone Application (SA), Modified Inclinometer (MI)

In a cross-sectional study by Kiatkulanusorn S et al (2023) with the objective to assess the concurrent validity, intra- and inter-reliability of five goniometric modalities, i.e. universal goniometer, inclinometer, digital inclinometer, smartphone application, modified inclinometer. The study involved 10 healthy individuals (five individuals for each gender) with an average age of 23.10 ± 3.25 years old. For standardised angle, the SEM and MDC for pair of devices comprising of UG, IC and DI were within 1º and 2º, respectively. The LOA was reported to be between -2.69º and 3.00º. Other than that, for devices pair of SA and MI showed a greater trend of SEM 0.92º to 1.32º, MDC 2º to 3º and LOA between -4.11º and -4.04º. For the human joint angle, device pairs UG, IC and SA reported SEM within 3°, MDC within 8°, 95% LOA between -10.98° and 8.41°. Whereas, device pairs MI and other devices have higher SEM 4°, MDS 7° to 9°, LOA -10.38° and -11.38°. Inter-rater reliability for standardised angle for all devices were reported to be excellent in between 0.980 to 0.999. However, the human joint angle reported the ICC to be moderate to excellent in between 0.697 to 0.975. [18 Level III]

5.1.5 Easy Angle® Digital Goniometer

Luedtke K et al. (2020) in a cross-sectional study for evaluating the validity, intra- and inter-rater reliability of the digital goniometer, Easy Angle® during flexion-rotation-test (FRT) in healthy individuals and patients with headache and/or neck pain. There were two cohorts in the study involving 62 patients in concurrent validity study and 50 patients in reliability study. In the concurrent validity part, the LOA for left rotation was reported -4.80° to 5.85° with mean difference of 0.53° (95% CI -0.15 to 1.29). Whereas, the LOA for right rotation was reported -6.39° to 6.17° with mean difference of -0.11° (95% CI -0.91 to 0.69). The ICC was reported to be good with ICC (2,1) of 0.97 for movement to both left and right. Measurements were deemed accurate supported by Bland Altman plot; the mean difference were 0.5º for the left side and 0.11º on the right side. Aside that, the inter-reliability for total FRT of the maximum right to maximum left was reported an agreement of 0.66 (95% CI 0.47 to 0.79; p<0.001; SEM 6.6°). Individually, the FRT ICC range to the left was 0.72 (95% Ci 0.56 to 0.83) and FRT ICC range to the right was 0.60 (95% CI 0.39 to 0.75). The LOA to the left was reported to be +9.8º and -9.02º and to the right was reported to be +11.52º and -12.39º with mean differences of 0.39º and 0.43º, respectively. Overall, the intra-rater reliability was excellent with ICC (3,1) values of more than 0.92. [1 Level III]

A cross-sectional study by Duffy E et al. (2024) with the objective to evaluate both intra- and inter-reliability and the preliminary normative reference values of the Easy Angle® Goniometer in measuring the hip joint ROM of the elementary school children. Twenty healthy children between five and ten years old were tested for flexion, abduction, extension, internal and external rotation of the hip motions. Good to excellent reliability were reported for intra-rater reliability of all hip joints ROM measurement conducted by two raters [ICC (3,1) = 0.888 to 0.961, Rater 1] [ICC (3,1) = 0.807 to 0.971, Rater 2]. Meanwhile, hip flexion reported highest ICC (3,1) of 0.961 and 0.971 for Rater 1 and Rater 2 respectively compared to the lowest measurement of hip extension reported of ICC (3,1) 0.888 by Rater

1 and 0.807 for Rater 2. The inter-rater reliability reported good to excellent hip joint ROM measurement as well. Highest ICC (3,1) 0.911 was reported for hip flexion in comparison to hip external rotation reported the lowest of ICC (3,1) 0.788. [19 Level III]

Another cross sectional related to Easy Angle® digital goniometer by Svensson M et al. (2018) focusing on the inter- and intra-rater reliability of Easy Angle® for the measurement of knee joints ROM and to observe any difference intra-rater reliability between new and experienced assessors. Twenty healthy participants with nine of them reported knee joint instability, meniscal tear injuries, patellar tendinosis, osteoarthritis and undefined pain. The intra-rater reliability reported to be ICC (3,1) 0.997 to 0.998 and inter-rater reliability reported to be ICC (3,1) 0.994. [21 Level III]

5.1.6 Smartphone goniometer application vs Universal Goniometer and Visual Estimation

A cross-sectional study by Koong DP et al. (2020) focusing on determining the validity and reliability of smartphone goniometer application for the assessment of elbow ROM in paediatric patients in comparison to universal goniometer (UG) and visual estimation. It included twenty patients (15 males and five females) with an average age of 10.5 years old who had previously had above-elbow mobilisation and/or injury treatment. Movements measured included maximal elbow flexion, extension, supination and pronation. Overall, all movements reported an excellent inter-rater reliability of ICC with an average of 0.97 for both UG and smartphone goniometer application and 0.92 for the visual estimation. The inter-rater reliability reported highest ICC for the extension and supination, meanwhile pronation reported lowest ICC based on Table 3. Intra-rater reliability, on the other hand, reported excellent correlation between visual estimation, smartphone goniometer application and UG with ICC ranging between 0.91 and 0.98 and 0.99, respectively. [20 Level III]

Measurement	ICC	95% CI
Visual estimation		
Flexion	0.89	0.69–0.96
Extension	0.97	0.96–0.98
Supination	0.96	0.90–0.98
Pronation	0.89	0.70–0.95
Goniometer		
Flexion	0.96	0.82–0.98
Extension	0.99	0.99–0.99
Supination	0.99	0.97–0.99
Pronation	0.94	0.86–0.98
Smartphone application		
Flexion	0.97	0.92–0.98
Extension	0.99	0.99–0.99
Supination	0.99	0.98–0.99
Pronation	0.95	0.91–0.98

CI, confidence interval; ICC, intraclass correlation coefficient

Table 5: Inter-rater reliability between raters for elbow ROM[28]

5.2 SAFETY

There was no study retrieved regarding the safety of the digital goniometer or the smartphone goniometer application. Malaysian Medical Device Authority (MDA) requires the registration of the device for Malaysian market. [7] US FDA classified goniometer as Class I (those that does not use electrode lead wires and patients cable) and Class II that uses electrode lead wires and patients cable. Both are exempted from pre-market notification. [29]

5.3 ECONOMIC IMPLICATION

There was no retrievable evidence on the cost-effectiveness or other economic analysis related to digital goniometer or smartphone application. A search in a local website, the digital goniometer costs [redacted][30], meanwhile, for smartphone goniometry-based application could range from [redacted] found in Apple apps store.

5.4 ORGANISATIONAL ISSUES

The handling of goniometer can be handled even by novice assessor as highlighted by Svensson M et al. (2018) given sufficient familiarisation and practice provided. [21] According to Duffy E et al. (2024), EasyAngle® Digital Goniometer can be considered as a reliable tool for the assessment of hip joint ROM for healthy paediatric aged between five to 10 years old with an establishment of proper protocol. [19] The calibration of the smartphone could not be performed by individual, unless it was performed by the manufacturer. Hence, Furness J et al. (2018) highlighted that validation or accuracy assessment should be conducted before commencing the test or by cross referencing with a geometric tool. [31]

5.5 LIMITATIONS

We acknowledge certain limitations in our review, which should be addressed when interpreting the findings. One reviewer selected and appraised the studies and verified by another reviewer. Although there was no language constraint throughout the search, only full-text English publications published in peer-reviewed journals were included in the report, which may have removed some relevant articles and reduced the number of studies we could do. Most of the studies were cross sectional studies, which mostly focus on the present time of the measurements taken. No long-term outcome being evaluated by the included studies.

6.0 CONCLUSION

Universal goniometer, digital goniometer and smartphone goniometry application demonstrated good to excellent performance for measuring joint ROM except for cervical joint. No safety issue reported and no major economic implication.

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8.0 APPENDIX

APPENDIX 1: LITERATURE SEARCH STRATEGY

Database: Ovid MEDLINE(R) ALL <1946 to January 19, 2024>
Search Strategy:

1. **REHABILITATION/**
2. **Habilitation.tw.**
3. **Rehabilitation.tw**
4. **1 or 2 or 3**
5. **Exercise therapy/**
6. **(rehabilitation adj1 exercise*).tw.**
7. **(exercise adj1 therapy*).tw.**
8. **(exercise adj1 therap*).tw.**
9. **5 or 6 or 7 or 8**
10. **HEMIPLEGIA/**
11. **9 and 10**
12. **ARTHROMETRY, ARTICULAR/**
13. **range of motion.tw.**
14. **RANGE OF MOTION, ARTICULAR/**
15. **digital goniometer.tw.**
16. **((joint or passive or active) adj3 range of motion).tw.**
17. **12 or 13 or 14 or 15 or 16**
18. **universal goniometer.tw.**
19. **conventional goniometer.tw.**
20. **traditional goniometer.tw.**
21. **twin axis electrogoniometer.tw.**
22. **18 or 19 or 20 or 21**
23. **9 and 17 and 22**

Other Databases
PubMed
INAHTA
US FDA

} Same MeSH and keywords as per MEDLINE search

APPENDIX 2: HIERARCHY OF EVIDENCE FOR EFFECTIVENESS

DESIGNATION OF LEVELS OF EVIDENCE

I	Evidence obtained from at least one properly designed randomized controlled trial.
II-I	Evidence obtained from well-designed controlled trials without randomization.
II-2	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.
II-3	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
III	Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris 2001)

APPENDIX 3: EVIDENCE TABLE

Available upon request

TECHNOLOGY REVIEW (MINI-HTA) :DIGITAL GONIOMETER

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