

# TECHNOLOGY REVIEW (MINI-HTA) PODOSCOPE FOR FOOTPRINT ANALYSIS

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
013/2024



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This technology review (mini-HTA) is prepared to assist health care decision-makers and health care professionals in making well-informed decisions related to the use of health technology in health care system, which draws on restricted review from analysis of best pertinent literature available at the time of development. This technology review has been subjected to an external review process. While effort has been made to do so, this document may not fully reflect all scientific research available. Other relevant scientific findings may have been reported since the completion of this technology review. MaHTAS is not responsible for any errors, injury, loss or damage arising or relating to the use (or misuse) of any information, statement or content of this document or any of the source materials.

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#### **EVIDENCE INFORMED DELIBERATIVE PROCESS**

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#### **EXECUTIVE SUMMARY**

#### **BACKGROUND**

Podoscope is a device design for static examination of the feet. Detailed analysis of the footprint obtained from podoscope will detect any abnormalities in the foot structure in order to provide the personalised and effective treatment. There are various types of podoscope machine available in the market including classic podoscope, photo podoscope, portable podoscope as well as digital podoscope.

Basically, podoscope able to identify pressure problem and determine the points of support and various characteristics or malformations of the foot that can lead to multiple conditions such as defect in posture as well as pain. The podoscope also capable to visualise information on disorders such as flat feet at all degrees and examining the distribution of the bearing surfaces and analysing the arch of a patient (high arches, excessive pronation, early detection of bunions (Hallux Valgus), hammertoes etc).

Currently, most of Ministry of Health facilities used a manual ink-mat method to assess and diagnose foot abnormalities either among adults or children. From the footprint image, the physiotherapist will manually measure the required information for further analysis. This method has limitation in that, it is time consuming and quite a sloppy process. The need to use innovative and more precise method in the assessment and management of foot deformity in the Malaysian population need to be addressed. Hence, it is timely that the review is requested by the National Head of Physiotherapy to address the need in providing more precise and efficient management of this condition in the country.

#### **OBJECTIVE/ AIM**

To assess the efficacy/effectiveness, safety and cost-effectiveness of podoscope in footprint analysis

#### **RESULTS:**

## Search results

A total of **60** records were identified through the Ovid interface and PubMed. After removal of duplicates and irrelevant titles, **31** titles were found to be potentially relevant and were screened using the inclusion and exclusion criteria. Of these, **29** relevant abstracts were retrieved in full text. After reading, appraising and applying the inclusion and exclusion criteria, **nine** studies were included while the other **20** studies were excluded since the studies either had different objectives and scope or narrative reviews. **Nine** full text articles were finally selected for this review comprised of one SR, four diagnostic accuracy studies and four cross-sectional studies.

#### Efficacy/Effectiveness

Podoscope showed comparable accuracy and excellent reliability with ink footprint methods and clinical assessment in determining foot deformity either in adult or paediatric patients; accuracy ranging from 90.5% to 96.50% and correlation ranging from ≥0.75 to >0.9, respectively. One study compared podoscope with radiograph in screening flatfoot among paediatric patients, the sensitivity for radiological parameter was 95.2% with an overall accuracy of 82% while podoscope was 85.7% and 67%, respectively. One SR among paediatric patients with Down's Syndrome found that there were very good values of the intra-class correlation coefficient (ICC) ranged from 0.984 to 0.995 of the included parameters index. Besides, the study also reported very good ICC values which were equal to or greater than 0.988 for all podiatric parameter indices.

The included studies also reported several advantages toward podoscope over ink-footprint. Podoscope provide high quality plantar surface image with high resolution images, foot's outer border was sharper and clearer than ink-mat method, and the measurement were using standard and valid software which able to minimise error during manual measurement. Podoscope also speed-up the whole foot-print analysis with improved data and image storing systems.

#### Safety

No safety issue reported regarding the use of podoscope.

#### **Organisation Issues**

There was no retrievable evidence specifically discussed on organisational issues of podoscope.

## **Economic Implication**

There was no retrievable evidence retrieved on cost-effectiveness of podoscope for footprint analysis. The price of digital podoscope is varies depending on the specification of the device.

#### CONCLUSIONS

Based on the review, podoscope showed good performance with strong correlation with ink-footprint manual measurement as well as clinical diagnosis by the experience assessors. However, when compared with radiograph, radiograph was more sensitive for flat foot than the podoscope. Overall, the podoscope will speed up the whole process of footprint analysis process with improved data and image storing systems. There were no issues on safety and no cost-effectiveness study retrieved on podoscope for foot deformity screening.

#### **METHODS**

Literature search was conducted by an *Information Specialist* who searched for published articles on podoscope for footprint analysis. The following electronic databases were searched through the Ovid interface: Ovid MEDLINE® In-Process & Other Non-Indexed Citations and Ovid MEDLINE® 1946 to 31 July 2024. Parallel searches were run in PubMed, US FDA and INAHTA database as well as CADTH. Some limitations applied during search (animal study). Additional articles were identified from reviewing the references of retrieved articles. The last search was performed on 31 July 2024.

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## **ABBREVIATIONS**

CA Clarke's angle

CI Chippaux-Smirak index Hernandez-Corvo Index

ICC intra-class correlation coefficient

SI Staheli Index

LED Light emitting diod
GTE Great toe extension
FPI Foot posture index
TA Talonavicular angle
TCA Talocalcaneal angle

CIA Calcaneal inclination angle ROC Receiver Operating Curve

AUC Area Under Curve

## 1.0 BACKGROUND

Podoscope is a device designed for static examination of the feet. Detailed analysis of the footprint obtained from podoscope will detect any abnormalities in the foot structure in order to provide personalised and effective treatment.<sup>1-2</sup> There are various types of podoscope devices available in the market including classic podoscope, photo podoscope, portable podoscope as well as digital or smart podoscope.<sup>3</sup>

Basically, podoscope able to identify pressure problem and determine the points of support and various characteristics or malformations of the foot that can lead to multiple conditions such as defect in posture as well as pain. The podoscope also capable to visualise information on disorders such as flat feet at all degrees and examining the distribution of the bearing surfaces and analysing the arch of a patient (high arches, excessive pronation, early detection of bunions (Hallux Valgus), hammertoes etc).<sup>3,4</sup>

Currently, most of Ministry of Health facilities used a manual ink-mat method to assess and diagnose foot abnormalities either among adults or children. From the footprint image, the physiotherapist will manually measure the parameter indices for further analysis. This method has limitation in that, it is time consuming and quite a sloppy process. The need to use innovative and more precise method in the assessment and management of foot deformity in the Malaysian population need to be addressed. Hence, it is timely that the review is requested by the National Head of Physiotherapist to address the need in providing more precise and efficient management of this condition in the country.

#### 2.0 OBJECTIVE / AIM

To assess the efficacy/effectiveness, safety and cost-effectiveness of podoscope in footprint analysis.

#### 3.0 TECHNICAL FEATURES

## 3.1 Conventional/manual measurement (Ink-mat method)

Ink-mat method is a graphic plantar-printing based on ink and paper that being used in footprint analysis. The footprint stamped on the graph paper illustrated the whole image of the plantar with high pressure points and weight imbalance as a darken areas (**figure 1.0-1.1**). The ink-mat method requires manual operation and manual calculation of footprint parameter index such as Arch index (AI), Chippaux-Smirak index (CSI) and Staheli index (SI) to assess any foot deformities.<sup>5</sup>



Figure 1.0: Manual analysis (Ink-Mat method)



Figure 1.1: Manual ink footprint

## 3.2 Podoscope

There are various types of podoscope devices which are characterised according to the built-up structure and also any technology installed within. As an example the built-up materials of the supporting structure such as metal, wood, and translucent surface like transparent glass or plastic back-illuminated top. A mirror to reflect the image to the camera or a scanner to capture the image of the footprint. Then, the captured image will be displayed on a computer or mobile phone through internet or USB cable for further analysis. For image analyser, software installed within the podoscope system like AutoCAD, MATLAB, Open CV library etc are used to measure the parameter index of any foot abnormality.<sup>6</sup>

#### i. Customised / low cost photo-podoscope

A custom low-cost photo-podoscope was designed as a device connected to a personal computer. This equipment enables acquisition of footprint images and estimation of the Arch

Index-Hernandez Corvo (AI-HC) index using an image processing technique. The basic structure of the device includes glass that is illuminated using light emitting diod (LED) lamps with a computer-controlled light intensity. The podoscope uses a fixed digital camera for acquiring colour images.<sup>7</sup>



Figure 2.0 Low cost photo-podoscope

## ii. Digital podoscope<sup>7,8</sup>

The podoscope is connected or built-in with a sensor that is connected to the computer via internet line or USB cable. The computer is installed with the analyser software.

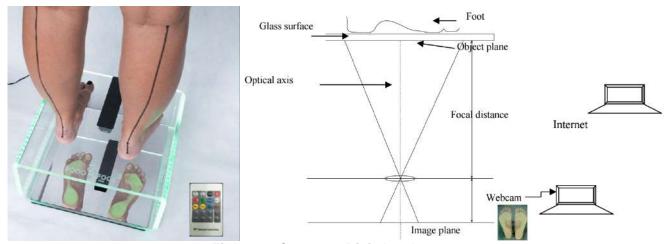


Figure 3.0 Computer-Digital podoscope

## General mechanism of Podoscope Analysis

Patients stand on a glass plate, then the reflected image from a mirror installed under the glass plate is seen. By using optical technique, either camera or scanner, the footprint image will blanch to different intensity levels. Different intensity levels are mapped to different color codes to obtain pressure distribution maps. Normally the optical podoscope made by camera or scanner is low cost but needs a smart software to analyse the foot problems such as flat feet or high arches.<sup>5</sup>

## Footprint parameter indices

On any foot printing image, several index parameters, such as Staheli arch index, Clark's angle and Chippaux-Smirak index (with the neural network processing) can be calculated. In general, Staheli arch index provides more accuracy after learning by neural network.<sup>5, 9</sup>

## i. Staheli Arch Index (AI)

Staheli Arch Index is the ratio of the minimum width of the midfoot arch region to the maximum width of the rearfoot region (**figure 4b**).<sup>10</sup>

The Al provides a link between the midfoot and the heel. The reference range is 0.600 to 0.699. Higher values determine a flattening or pronation trend and lower values a trend toward a cavus foot.<sup>9</sup>

## ii. Chippaux-Smirak Index (CSI)

Chippaux-Smirak Index is a ratio of the minimum width of the midfoot arch region to the maximum width of the forefoot region (**figure 4b**).<sup>10</sup>

The CSI evaluated the occupation of midfoot on a smooth surface. The mean  $\pm$ SD reference value is 35  $\pm$  10. Higher value determines a flattening or pronation trend, and lower values is a trend toward a cavus foot.<sup>9</sup>

#### iii. Clark's angle

Clark's angle is the angle between the line connecting the medial side-most points of the heel and metatarsal regions and the line connecting the lateral-most point on the medial foot border to the medial-most point of the metatarsal region (**figure 4a**).<sup>10</sup>

The CA evaluates the foot's longitudinal arch. The mean  $\pm$ SD reference range is  $38^{\circ} \pm 7^{\circ}$ . Higher values determine a trend toward a cavus foot and lower values a trend toward flattening or pronation.<sup>9</sup>

## iv. Arch length index

Arch length index is the ratio of the length of the line between the medial area-most points of the metatarsal and heels regions to the border length of the arch outline between these points (**figure 4c**).<sup>10</sup>

#### v. Arch Index

Arch index is the ratio of the area of the middle third of the toeless footprint to the overall toeless footprint area. A line is drawn between the centre point of the second toe and the posterior-most point on the heel. Two parallel lines perpendicular to the line are drawn to devide the toeless footprint area into equal thirds (**figure 4d**).<sup>10</sup>

#### vi. Footprint index

Footprint index is the ratio of the non-contact area to the contact areas of the toeless footprint. The non-contact area is the area between the medial borderline axis formed by the medial-most points of the metatarsal and heel regions of the footprint and the medial border of the footprint outline. The contact area is the area of the toeless footprint (**figure 2e**).<sup>10</sup>

#### vii. Truncated arch index

Truncated arch index is the ratio of the non-contact area (the arch area) to the truncated footprint area. The non-contact area is the area between the medial border line and the medial footprint outline. The truncated footprint area is bounded by the area between the lines perpendicular to the medial borderline axis of the footprint through the medial-most points of the metatarsal and heel regions of the footprint (**figure 4f**).<sup>10</sup>

## viii. Hernandez-Corvo Index (HI)

Hernandez-Corvo Index is a widely used set of indices that measures the plantar contour and classify feet into seven types by occupation: flat (0%-34%), flat-normal (35%-39%), normal (40%-54%), normal-cavus (55%-59%), cavus (60%-74%), strong cavus (75%-84%) and extreme cavus (85%-100%).

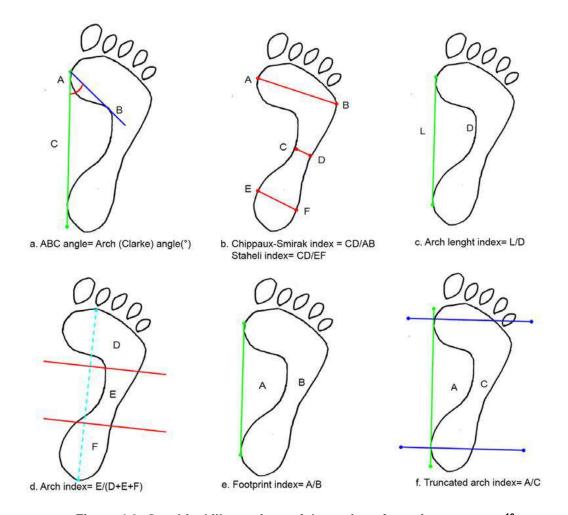


Figure 4.0: Graphical illustartions of the various footprint parameter<sup>10</sup>

## Types of Foot Deformity

There are various types of foot deformities. Some are present at birth.<sup>11</sup>

## i. Splayfoot

Metatarsal bones spread out and the front end of the foot becomes wider. As a results, more pressure is put on the middle bones in the forefoot that resulted in pain and make the skin hard and thick that lead to calluses. People with splayfeet are also more likely to develop bunions (hallux valgus).<sup>11</sup>

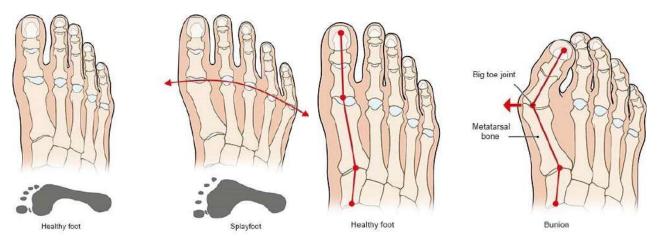


Figure 5.0: Splay foot and bunion

## ii. Fallen arch / flat foot / pesplanus

In fallen arches, the hollow arch under the foot is flatter than usual. Extreme cases of fallen arches are referred to as flat feet where the entire sole of the foot touches the floor. Fallen arches and flat feet usually develop over time.<sup>11</sup>



Figure 6.0 Fallen arch / flat foot

#### iii. Pronated foot

In pronated foot, the heel leans inward. However, the problem usually started after several decades at around the age of 30 or 40.<sup>11</sup>

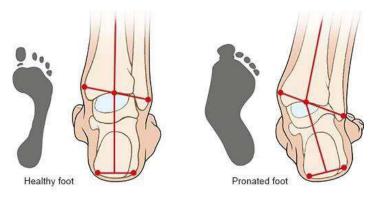


Figure 7.0 Pronated foot

#### iv. High-arched feet / pescavus

In high-arched feet, the individual has unusually high foot arch and the upper surface of the foot (the instep) is higher than normal. Thus, the ball of the foot has to carry more of the weight. This can lead to pain and calluses (areas of hard, thick skin). The problem also increases the likelihood of ankle injuries and claw toes.<sup>11</sup>



Figure 8.0 High-arched feet

## 4.0 METHODS

Literature search was conducted by the author and an *Information Specialist* who searched for full text articles on podoscope in foot deformity screening.

#### 4.1 SEARCHING

The following electronic databases were searched through the Ovid interface:

MEDLINE® In-Process and Other Non-Indexed Citations and Ovid MEDLINE® 1946 to 31
 July 2024

#### Other databases:

PubMed

Other websites: US FDA, INAHTA, CADTH

Keywords: foot deformities, podoscope, podiatry

General databases such as Google and Yahoo 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. However, at the end only English full text article were included. **Appendix 1** showed the detailed search strategies. The last search was conducted on 31 July 2024.

#### 4.2 **SELECTION**

A reviewer screened the titles and abstracts against the inclusion and exclusion criteria. Relevant articles were then critically appraised using *Critical Appraisal Skills Programme* (CASP) checklist for diagnostic accuracy study, JBI for cross-sectional study and ROBIS for SR. Data were extracted and summarised in evidence table as in **Appendix 2**.

The inclusion and exclusion criteria were:

#### Inclusion criteria:

a.	Population	Foot deformity/foot abnormalities
b.	Intervention	Podoscope
C.	Comparator	i. No comparator ii. Conventional / standard method
d.	Outcomes	i. Efficacy and effectiveness ii. Safety

e.	Study design	SR, RCT, diagnostic accuracy study, cross-sectional study
f.	Full text articles p	published in English

#### **Exclusion criteria:**

|--|

## 5.0 RESULTS

#### Search results

An overview of the search is illustrated in **Figure 9**. A total of **60** records were identified through the Ovid interface and PubMed. After removal of duplicates and irrelevant titles, **31** titles were found to be potentially relevant and were screened using the inclusion and exclusion criteria. Of these, **29** relevant abstracts were retrieved in full text. After reading, appraising and applying the inclusion and exclusion criteria, **nine** studies were included while the other **20** studies were excluded since the studies either had different objectives and scope or narrative reviews. **Nine** full text articles finally selected for this review comprised of one SR, four diagnostic accuracy studies and four cross-sectional studies.

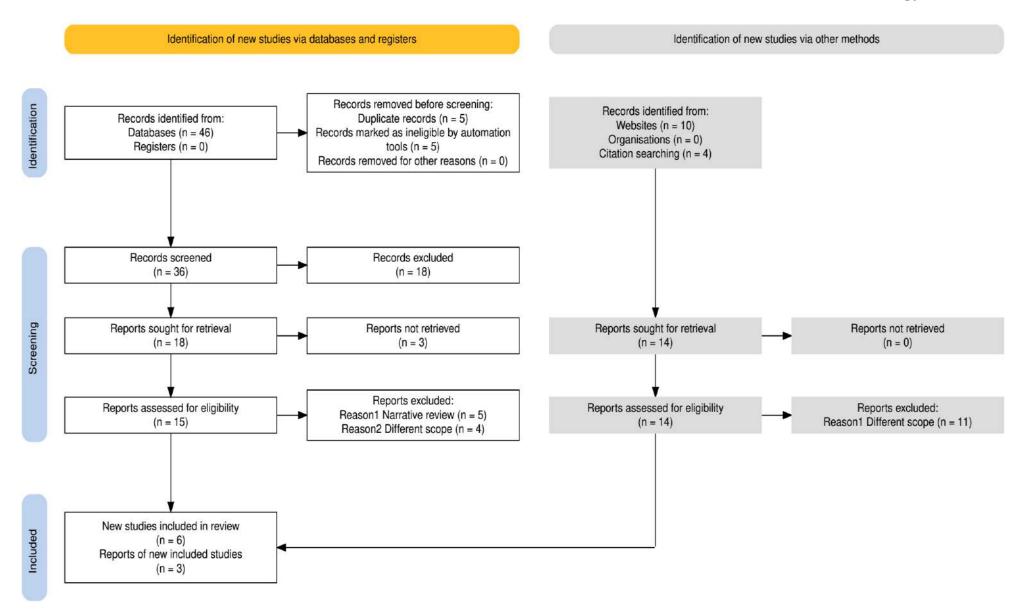


Figure 9.0: Flow chart of retrieval of articles used in the results

## Quality assessment of the studies

The risk of bias (RoB) in the included studies were assessed using domain-based evaluation. Tools that are being used by MaHTAS to assess the risk of bias are adapted from the CASP checklist (for diagnostic accuracy studies), and ROBIS (for systematic review). This is achieved by answering a pre-specified question of those criteria assessed and assigning a judgement relating to the risk of bias as either:



Judgement of overall risk of bias is high if any one of the domain concerned has high risk of bias. If more than two domains are judged as uncertain, it was categorised as moderate RoB. While if there is less than two domains judged as unclear than it was categorised as low RoB.

The risk of bias for the SR was considered moderate because some information in D2, and D6 was not mentioned clearly in the study. Besides, no meta-analysis was conducted. Meanwhile for the diagnostic accuracy studies, the risk of bias can be considered low to moderate because there was study lack of information on subject's condition during recruitment. The results of the risk of bias assessment of the included studies are summarised in **Figure 10.1**, and **10.2** 

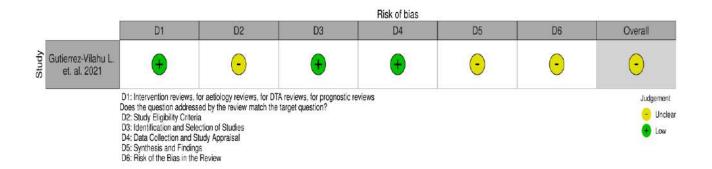


Figure 10.1: Risk of Bias of Systematic Review

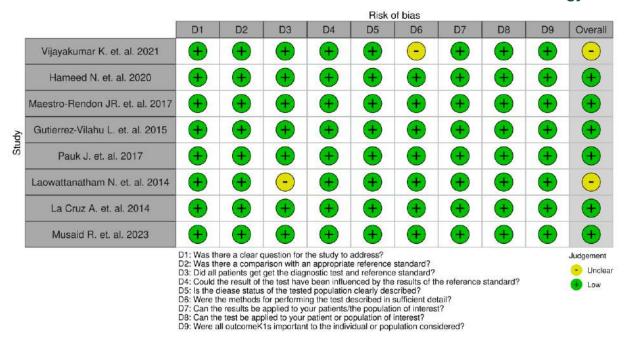


Figure 10.2: Risk of Bias of Diagnostic Accuracy Studies

### 5.1 EFFICACY / EFFECTIVENESS

Vijayakumar K. et. al. (2021) conducted a diagnostic accuracy study to assess the validity of the custom made podoscopic images compared with ink footprint methods using the same footprint parameter indices. The ink footprint involved ink pad where the patients stamp their footprint on breadth of paper and a measurement of the parameter were conducted manually. Meanwhile, the custom-made podoscope was made-up from unbreakable glass as a stamped surface, wood as a frame and document scanner where the images of the footprint were transferred to a computer and the measurement was conducted with AutoCAD software. The parameter indices were accuracy of an arch angle (AA), Chippaux-Smirak Index (CSI), Staheli Index (SI) and Arch Index (AI). The study involved 416 healthy participants aged between 21 to 65 years old. All the participants went both methods for further analysis of the accuracy and reliability of the parameter indices obtained from both methods. The authors observed the distribution of normal, pesplanus and pescavus of both methods, assess the intra-rater reliability of ink footprints and podoscopic image by intraclass correlation (ICC) and interpreted their reliability. The findings for the observations were tabulated in **Table 1 - 3**. Both methods were comparable with 96.50% accuracy in determining foot deformity. On the other hand, the study also found that custom-made podoscopic method had excellent reliability (≥0.75) compared with the ink-footprint method. Although the ink pad method was a standard that widely used for footprint analysis, the authors reported several disadvantages compared to podoscope which were inked did not properly stamp over the plantar surface, poor absorption or excessive absorption of ink on paper, manuals error while measuring the parameter indices for the ink footprint and the ink

footprint's accuracy lost after more than three or four trial measurements. On the other hand, they also found that podoscope identified the foot's outer border sharper and clearer than ink mat method. Besides, the podoscope scan the overall plantar surface to provide high quality of the plantar surface image with high resolution images and the measurement were using standard and valid AutoCAD software. Compared with ink footprint, the podoscope required shorter time from image taking and analysing.<sup>12</sup>

Table1: Distribution of different types of arches foot determined using ink footprint and podoscope method (n = 416)

Variables	lnk fo	ootprint method	Scar	ner method
	M	F	M	F
Normal Arch	63.30%	54.60%	58.00%	53.50%
High Arch	16.55%	17.80%	19.50%	18.50%
Flat Arch	20.15%	27.60%	22.50%	28.00%

<sup>\*</sup>M = male; F = female

Table 2: Standard deviation (SD), intraclass correlation (IC), standard error (SE), IC - p>0.01

Parameters	lnk f	ootprint		Scann	er footpri	nt	95% C.I
	Mean (SD)	IC	SE	Mean± SD	IC	SE	
AA	43.3(3.2)	0.98	0.89	42.1(3.6)	0.98	1.74	0.71-0.69
CI	35.7(1.9)	0.97	0.18	34.3(3.8)	0.96	1.29	0.66-0.79
SI	0.95(0.04)	0.99	0.13	0.78(0.04)	0.95	1.38	0.66-0.68
Al	0.24(0.12)	0.98	0.16	0.23(0.17)	0.99	1.07	0.68-0.87

<sup>\*</sup>AA = Arch angle; CI = Chippaux-Smirak Index; SI = Staheli Index; AI = Arch Index

Table 3: Diagnostic accuracy analysis

Statistics	Values	Confidence interval 95% CI
PPV	91.73%	86.48% - 95.32%
NPV	100%	100%
Accuracy	96.50%	95.80% - 98.87%
Sensitivity	100%	98.14% - 100%
Specificity	94.68%	93.43% - 98.66%

<sup>\*</sup>PPV = positive predictive value; NPV = negative predictive value

Hameed N. et. al. conducted a diagnostic accuracy study to compare between radiograph and podoscope methods in diagnosing paediatric flatfoot. Clinical diagnosis was gold standard for this study. The samples were 84 children (3-10 years old) who were recruited into two groups. The control group consisted of 42 children with normal feet morphology and the intervention group was 42 children with flat foot (flat foot group). Before undergoing radiography and podoscope methods, all children were clinically and physically examined. The examinations involved were great toe extension (GTE), photographic assessment and foot posture index (FPI). Meanwhile for podoscope the parameter indices measured were CA and AI and the radiology was looking at Talonavicular angle (TA), Talocalcaneal angle (TCA) and Calcaneal inclination angle (CIA). **Table 4** showed the summary and findings of the assessment conducted. In gold standard assessment, 40 children in the flat foot group were

found to be flat footed on radiological measurements and 36 on podometric measurements. Meanwhile, two children on x-rays and six on podoscope were normal in all measurements but were flat footed clinically. Based on individual parameter, a further breakdown of these children into flat foot and normal category was in Table 5. By keeping the clinical diagnosis as a gold standard, the sensitivity for radiological parameter was 95.2% with the overall accuracy of 82%. On the other hand, for podoscope, the sensitivity was 85.7% with the overall accuracy of 67%. Collectively radiographic parameter was found to be more sensitive in diagnosing flat foot than podoscope parameter indices. However, individually the podometric parameter were more sensitive. The authors also further analysed to determine how well each method can distinguish between diseased and normal subjects through Receiver Operating Curve (ROC) analysis. The ROC analysis showed that Area Under the Curve (AUC) was more for podoscope parameter indices (AUC = 0.702) compared to radiology (AUC = 0.667). Among all diagnostic parameter involved, the AUC was highest for CA (AUC = 0.952) and lowest for Calcaneal inclination angle (AUC = 0.464). Among the radiological parameter, highest AUC was for Talonavicular angle (AUC = 0.750). The authors also look into correlation between different radiographic and podometric parameter. They found that strong significantly positive correlation existed between AI and TCA (r = 0.805, p = 0.000) while a significantly negative weak correlation existed between AI and CA (r = -0.367, p = 0.017) which meant that increased in AI was associated with decreased in CA and vice versa.13

Table 4: Summary of the findings on physical and clinical assessment, radiology and podoscope analysis

	_	anaiysis		_
Photography	v		O I V	•
Parameters		Findings		
rarameters	Observations	Control	Flat foot group	
GTE	Present/absent	Present in all	26.2% absent 73.80% Present	
Photography	Back view: Hind foot valgus	Absent	12 had hind foot valgus without fore both present.	
т посодгарну	Front view: Forefoot abduction	Absent	1 had fore foot abduction without hind absent	foot valgus 9 had both
	Pronated foot	0	50%	
FPI	Supinated foot	0	0	
	Neutral position	100%	50%	
Radiography				
	Control group		Flatfoot group	
	Mean±SD	Range	Mean±SD	Range
Talonavicular angle	5.65±1.43	3-7.2	6.50±0.57	3-20
Talocalcaneal angle	37.26±7.5	25-49	40.52±0.49	25.3-52.5
Calcaneal inclination angle	19.57±2.93	16-25.3	19.93±5.25	12-37
Podometry				
	Control group		Flatfoot group	
	Mean±SD	Range	Mean±SD	Range
Arch Index	0.32±0.005	0.32-033	0.32±17.58,	0.21-0.46
Clark's Angle	46.66±4.60	37-54	28.92±16.20	18-45

Table 5: Parametric details of flat foot sub types

						Flatfoot			
	Parameters	Normal	Total		Flexib	ole		Rigi	d
			10111	n	Mean	Range	n	Mean	Range
	Talonavicular angle	15	27	14	8.45°	7–9.3°	13	7.93°	7–20°
X-ray	Talocalcaneal angle	21	21	10	47.22°	44-52.5°	11	48.16°	45-52.5°
	Calcaneal Inclination angle	12	30	22	17.14°	12-22.5°	8	17.75°	12-19.4°
Podometry	Arch Index	8	34	13	0.36	0.33-0.46	15	0.36	0.32-0.45
r odometry	Clark's angle	4	38	20	28.85°	21–31°	15	25.86°	18-31°

Table 6: Sensitivity, specificity of the radiological and podoscope analysis

Parameters	TP	TN	FP	FN	Sensitivity*	Specificity*	PPV	NPV	Accuracy
Radiological paran	neters								
Talonavicular angle	27	39	3	15	64% (48–78%)	92.86% (80.5–98.5%)	90%	72.2%	82%
Talocalcaneal angle	21	38	4	21	50% (34–97%)	90.4% (77–97.3%)	84%	64%	70%
Calcaneal Inclination angle	30	36	6	12	71% (55–84%)	85.7% (71–94.5%)	83%	75%	78.5%
Podometric param	eters								
Arch Index	34	23	19	8	81% (65–91%)	54.7% (38.6–70%)	64%	74%	67.8%
Clark's angle	38	38	4	4	90% (77–97%)	90% (77–97%)	90.5%	90.5%	90.5%

TP=True positive, TN=True negative, FP=False Positive, FN=False Negative. \*Sensitivity and specificity with 95% CI. PPV=Positive predictive value, NPV=Negative predictive value

Pauk J. et. al. conducted cross-sectional study to propose a new computer-aided system for automatic foot parameter indices identification based on images taken from podoscope. The study also to examine validity and reliability of the proposed system as a practical tool for assessment of foot posture in adult population compared to foot parameter indices counted manually. The new-computer aided tool was regular podoscope equipped with computer aided-system where the parameter indices were measured within the software. Meanwhile the manual tool was regular podoscope where the image was printed in 2D form and any measurement was conducted manually. The parameter indices compared were Clarke angle (CA), KY index of Sztriter-Godunov (KY), Heel angle (Gamma) and Weysflog index (WI). The study involved 24 male and female students with mean age of 20.1 ± 0.6 years. The foot will be classified as normal arch (CA >42° and <48°) flat foot arch (CA >°42) and high arch (CA >55°). After all the measurements completed, the results showed that foot parameter calculated manually with podoscope and digital image were of a similar reliability to the same parameter derived using a computer-aided system (Table 7). The Spearman's rank correlation suggests a strong positive relationship between parameter from computer-aided system and the parameter counted manually (R > 0.9). The differences between parameter's value obtained from the two methods were not statistically significant (p > 0.05). However, the parameter counted manually are subjective and depend on experimenter's experience.<sup>14</sup>

Table 7: Mean values (±SD) of foot parameter

Variable	Computer-aided system	Manual	Comparison system	computer-a	
	Mean	Mean	Difference	<i>p</i> -value	R
Clarke angle [degree]	40.9 (11.3)	39.6 (10.9)	1.3	0.65	0.97
'KY' index of Sztriter-Godunov	0.42 (0.1)	0.45 (0.1)	-0.03	0.48	0.98
Heel angle (Gamma) [degree]	17.3 (2.4)	17.3 (2.4)	0.00	0.94	0.97
Weysflog index	2.56 (0.15)	2.53 (0.14)	0.03	0.45	0.93

Maestra-Rendon JR. et. al. conducted a diagnostic accuracy study to introduce a sensor that integrates the capture of the plantar footprint, the analysis of the image and the interpretation

of the results through a quantitative evaluation. To develop the system, the authors upgraded the regular podoscope with generic camera which was connected to a computer equipped with operative system or software for the analysis (upgraded podoscope). The parameter indices used to analyse and evaluate the foot images were Staheli arch index (SI), CA and Chippaux-Smirak index (CI). Forty subjects between the ages of 18 and 24 were involved in the study. They were presented with different types of foot conditions either cavus foot, normal foot and flat foot. Ink mat was choosing as the reference standard and was calculated manually. Another comparator was digital measurement where the authors convert the manual measurement of ink mat into digital form. All patients went both footprint measurement methods; the upgraded podoscope and ink mat (manual measurement or digitalised). The relationship between the three methods was verified using Pearson correlation coefficient and was shown in **Table 8**. Based on the analysis, it showed that there was strong correlation among those techniques (>0.96). 15

Table 8: Comparison of values obtained from the evaluated methods and their respective correlation coefficient

<b>Compared Methods</b>	Correlation Coefficient 1
Ink mat (manual) vs. Ink mat (digitalized)	0.9618
FPDSS <sup>2</sup> vs. Ink mat (manual)	0.9619
FPDSS <sup>2</sup> vs. Ink mat (digitalized)	0.9938

Gutierrez-Vilahu L. et. al. conducted diagnostic accuracy study to assess the reliability and validity of a new method of footprint assessment in a healthy population using Photoshop CS5 software (computerised podoscope). Manual measurement of the footprint parameter indices was considered as a gold standard. The parameter indices involved were Hernandez-Corvo index (HI), CI, AI and CA. The study involved 21 individuals with an age range of 15 to 24 years old. Intraclass correlation coefficient (ICC) was calculated for all the footprints (42 prints) and for each of the parameter indices in order to determine the concordance level. The reliability of the set of indices with computerised podoscope showed impressive ICC as simplified in **Table 9.** Validation was conducted and the two methods were compared. As shown in **Table 10**, all the ICC values were higher than 0.994.9

Table 9: Reliability of repeated measures of the 21 foot prints according to Photoshop CS5 techniques

Podiatric Medical Index	ICC (95% CI)
HI	0.985 (0.968-0.993)
CSI	0.993 (0.986-0.997)
Al	0.995 (0.989-0.998)
CA	0.989 (0.977-0.995)

Abbreviations: AI, Staheli Arch Index; CA, the Clarke angle; CI, confidence interval; CSI, Chippaux-Smirak Index; HI, Hernández-Corvo Index; ICC, intraclass correlation coefficient.

Table 10: ICCs (95% CIs) compare the Gold Standard manual method with the computerised method

Podiatric Medical Index	ICC (95% CI)
HI left	0.998 (0.995-0.999)
HI right	0.994 (0.985-0.998)
CSI left	0.999 (0.997-1)
CSI right	1.000 (0.999-1)
Al left	0.998 (0.995-0.999)
Al right	0.999 (0.999-1)
CA left	0.999 (0.998-1)
CA right	0.999 (0.997-0.999)

Laowattanatham N. et. al. conducted a diagnostic accuracy study of digital podoscope with algorithm for automatically assessing the deformity and calculating the foot parameter indices compared to standard method (Harris-mat or ink-mat method). The digital podoscope proposed was built-up based on low-cost optical scanners that was connected to a computer with integrated software. With the software, not only the measurement but the footprint image will appear in different colour levels of a plantar structure and plantar pressure which later on classified the foot conditions. The study involved 25 participants who have been identified with foot problems and undergo both footprint methods. One of the example of footprints images from both methods were in **Figure 11**. The colour mapped image from the smart digital podoscope in Figure 11B able to show the foot deformity; red colour indicated pressured area and other foot problems more than other colours. Meanwhile the clear correlation which obtained from a Harris Mat also can be seen from the ink footprint in Figure **11A**. The foot deformity was classified into three categories; high arch, normal foot and flat foot. Measurements for foot parameter indices for right and left foot of the participants from both methods were shown in Table 11(a) and Table 11(b). Based on the results, the foot length differences were within ±1 mm and the ratio foot parameter indices was within ±1% different.5

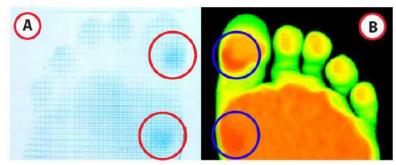


Figure 11.0: Example of pressure ulcer point from Harris Mat (A) and Smart Digital Podoscope (B)

Table 11 (a): Results of Foot Parameter indices (Left foot)

Foot	Tools	Foo	ot index a	analysis	
deformity	10015	Foot length (mm.)	AB (mm.)	BC (mm.)	Ratio (%)
	Harris Mat	265.26	25.21	52.11	32.60
High arch	Digital Podoscope	264.52	23.40	50.85	31.52
Difference value Mat and Digit		0.74	1.81	1.26	1.08
N. I.C.	Harris Mat	253.52	35.42	36.96	48.93
Normal foot	Digital Podoscope	252.94	34.75	37.80	47.89
Difference value between Harris Mat and Digital Podoscope		0.58	0.67	0.84	1.04
771	Harris Mat	251.65	48.18	26.10	64.86
Flatfoot	Digital Podoscope	250.89	46.50	24.95	65.08
Difference value Mat and Digit		0.76	1.68	1.15	0.22

Table 11 (b): Results of Foot Parameter Index (Right foot)

Foot	Tools	Foo	t index analysis		
deformity	10013	Foot length (mm.)	AB (mm.)	BC (mm.)	Ratio (%)
*** 1	Harris Mat	264.25	28.68	49.23	36.81
High arch	Digital Podoscope	263.91	27.90	47.70	36.90
	e between Harris ital Podoscope	0.34	0.78	1.53	0.09
	Harris Mat	257.14	36.12	37.63	48.97
Normal foot	Digital Podoscope	256.21	37.86	39.58	48.89
	e between Harris ital Podoscope	0.93	1.74	1.95	0.09
El .C .	Harris Mat	253.21	51.45	16.81	75.37
Flatfoot	Digital Podoscope	252.66	50.32	17.42	74.28
	e between Harris ital Podoscope	0.55	1.13	0.61	1.09

La Cruz A. et. al. conducted a cross-sectional study to validate study of photo-podoscope in footprint assessment. The study involved footprint measurement with traditional podoscope compared to specialist evaluation on image generated from the photo-podoscope. Both methods were compared to semi-automatic results obtained from software that connected to the photo-podoscope in order to validate the device. The study involved children aged three to six years old. There were two phases experiment, phase one involved 30 children who had previously foot assessment made by the specialist using traditional podoscope. Next, the same children were evaluated using the photo-podoscope device and with Arch Index Hernandez-Corvo (AI-HC) measurement to classify the foot type. Based on the assessment, the authors carried out concordance evaluation between results from the experts and photopodoscope. The concordance was Kappa, k = 0.63 (substantial concordance). The result indicates a high degree of agreement between expert assessment and the result obtained with photo-podoscope. Second phase experiment was carried out to evaluate the concordance between observers. At this phase, 40 children with aged of three to six years old were involved and evaluated by inter-expert through a triple-bind study. Three experts evaluated every patient based on image captured by photo-podoscope without seeing the patient. Fleiss Kappa was used for the concordance analysis and the results showed that k = 0:42 for left feet and k = 0:36 for right foot which considering as fair to good agreement evaluating the left feet and poor agreement evaluating the right foot, between observers. 16

Musaid R. et. al. conducted a cross-sectional study to assess a simple, low-cost podoscope in plantar footprint assessment. The podoscope was custom made with lowest feasible cost using affordable resources (iron metal for frame, tempered glass, LED lights, digital camera) and were connected to computer which was installed with analytics software. The proposed

podoscope was compared with BTS P-WALK methods and ink-foot prints as the standard reference. The parameter index assessed were AI, CI and SI. Ten samples were tested by the low-cost podoscope and the findings from the device will be approved by an expert. The validation results of the podoscope, the BTS P-WALK and ink-mat were reported in **Table 12** where the result showed a comparable AI among those three techniques. The authors also emphasised on advantages of the podoscope over ink-foot print and BTS P-WALK techniques where the podoscope improved image storing systems as well as retain the footprints data for a very long time. Besides the podoscope also able to eliminate human mistakes and speeds up the whole procedure of screening the foot abnormalities.<sup>17</sup>

DEVICE	AI		STATE	
	LF	RF		
Podoscope	0.22	0.25	Normal foot	
BTS P-WALK	0.22	0.25	Normal foot	
Foot print by ink	0.22	0.25	Normal foot	

Gutierrez-Vilahu L. & Guerra-Balic M. (2021) conducted an SR to identify the podometric measurement tools used to classify foot deformity in the population with Down's Syndrome. Eleven studies were included where all the studies used various types of footprint tools with standardise parameter indices to classify the foot types in subjects with Down's Syndrome. Out of the 11 studies, two studies assessed the reliability of those tools for Down's Syndrome population. Based on the included studies, the footprint tools used were podoscope, pressure-sensitive mat, PressureStatTM carbon paper, and a 3D scanner. The parameter indices calculated were AI, HI, CI, SI and CA. Based on the review, the authors found that the Al was the most common parameter indices reported in seven included studies. Based on reliability test from the included study with optical podoscope and Photoshop software, the authors reported that all the parameter's indices showed very good values of the intra-class correlation coefficient (ICC) ranged from 0.984 for the HI to 0.995 for the CA. The validity testing also found very good ICC values which were equal to or greater than 0.988 for all the podiatric parameter indices. Meanwhile in another study with 3D foot scanning, the intra-rater reproducibility (ICC ranged from 0.74 to 0.99) and inter-rater reproducibility (ICC ranged from 0.73 to 0.99) values indicated moderate to excellent reliability for all foot dimension measurements. Overall, the SR found for patients with Down's Syndrome population, there

was a need to determine the reliability and validity of the footprint measurement tools used for clinical classification of the foot deformity.<sup>18</sup>

## 5.2 SAFETY

No safety issue reported regarding the use of podoscope.

## 5.3 ORGANISATIONAL ISSUES

There was no retrievable evidence specifically discussed on organisational issues of podoscope.

#### 5.4 ECONOMIC IMPLICATION

There was no retrievable evidence retrieved on cost-effectiveness of podoscope for footprint analysis. The price of digital podoscope is varies depending on the specification of the device (price quoted from the requestor: digital podoscope around RM40,000 – RM55,000).

## 5.5 LIMITATIONS

We acknowledge some limitations in our review and these should be considered when interpreting the results. Besides, only English full text articles were included. There is also related full text articles could not retrieve because of database limitation.

## 6.0 CONCLUSION

Based on the above review, podoscope showed good performance with strong correlation with ink-footprint manual measurement as well as clinical diagnosis by the experience assessors. However, when compared with radiograph, radiograph was more sensitive for flat foot than the podoscope. Overall, the podoscope will speed up the whole process of footprint analysis process with improved data and image storing systems. There were no issues on safety identified and no cost-effectiveness study was retrieved on podoscope in foot deformity screening.

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## 8.0 APPENDIX

#### **APPENDIX 1: LITERATURE SEARCH STRATEGY**

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to August 28, 2024>, EBM Reviews - ACP Journal Club <1991 to August 2024>, EBM Reviews - Database of Abstracts of Reviews of Effects <1st Quarter 2016>, EBM Reviews - Cochrane Clinical Answers <August 2024>, EBM Reviews - Cochrane Central Register of Controlled Trials <July 2024>, EBM Reviews - Cochrane Methodology Register <3rd Quarter 2012>, EBM Reviews - Health Technology Assessment <4th Quarter 2016>, EBM Reviews - NHS Economic Evaluation Database <1st Quarter 2016>

- 1. Foot Deformities/
- 2. foot deformit\*.tw.
- 3. metatarsal deformit\*.tw.
- 4. Podiatry/
- 5. podiatr\*.tw.
- 6. chiropody\*.tw.
- 7. Flatfoot/
- 8. acquired adult flatfoot deformity.tw.
- 9. congenital vertical talus.tw.
- 10. convex foot.tw.
- 11. convex pes valgus.tw
- 12. (flat adj1 (feet or foot)).tw.
- 13. flatfeet.tw.
- 14. flatfoot.tw.
- 15. flexible flatfoot.tw.
- 16. pes planus.tw.
- 17. rigid flatfoot.tw.
- 18. rocker bottom foot.tw.
- 19. rocker-bottom foot.tw.
- 20. splayfoot.tw.
- 21. (talipes adj1 (calcaneovalgus or valgus)).tw.
- 22. vertical talus.tw.
- 23. podoscope.tw.
- 24. digital podoscope.mp.
- 25. (digital adj podoscope).tw.
- 26. footprint measurement.mp.
- 27. footprint measurement.tw.

keywords as per MEDLINE search

#### **Other Databases**

INAHTA

**US FDA** 

Technology EBM Reviews Health Assessment EBM Reviews - Cochrane database of systematic reviews EBM Reviews - Cochrane Central Registered Same MeSH, keywords, limits used as per of Controlled Trials EBM Reviews - Database of Abstracts of MEDLINE search **Review of Effects** EBM Reviews - NHS economic evaluation database PubMed Same MeSH and

# APPENDIX 2: EVIDENCE TABLE

(Available upon request)

TECHNOLOGY REVIEW (MINI-HTA) PODOSCOPE FOR FOOTPRINT ANALYSIS

e ISBN 978-967-2887-86-7



MAHTAS (online)