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Research Article

The Accuracy and Reliability of Plantar Pressure Measurements for the Early Diagnosis of Foot Deformities in Patients Suffering from Rheumatoid Arthritis

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ABSTRACT

Aim: Pedobarographic analysis may be employed to quantify foot function, however, the value of pedobarographic analysis as a diagnostic tool for the screening of recently diagnosed Rheumatoid Arthritis (RA) patients remains uncertain. The aim of this systematic review was to: a) assess the different instruments used to analyse plantar pressure; b) to report on the technical considerations associated with manual and automatic masking and c) to assess the validity together with the inter- and intra-observer reliability of pedobarographic analyses for identification of pathological profiles in patients suffering with RA.

Method: Following the PRISMA guidelines, a literature search was undertaken using a variety of computerised bibliographic databases. The Quality Appraisal of Diagnostic Reliability was employed to assist in the analysis of reliability.

Results: A review and analysis of the literature found only 20 papers with relevant reliability and accuracy.

Conclusion: The literature concerning the validity and reliability of pedobarography in the screening for early onset foot deformities in RA patients has not been proven. Although the forefoot has been identified as a common area of the plantar surface where deformities occur in RA, there are very few studies that demonstrate any subtle changes that could forecast forefoot deformities in asymptomatic RA patients.

Keywords: Accuracy; Reliability; Plantar pressure; Inflammatory arthritis; Progressive foot impairment; QAREL

Introduction

Rheumatoid Arthritis (RA) is a chronic inflammatory disease which commonly affects the feet; characterised by synovial inflammation and progressive destruction of the metatarsophalangeal articular surfaces. Foot deformities are manifest in the majority of RA sufferers and include functional changes such as painful joints, muscle weakness, altered gait, decreased postural stability and an increased risk of ulceration when left untreated [1,2]. The manifestation of such foot complaints can affect the everyday activities of RA patients particularly postural control, ambulation and other weight bearing functions [2]. Progressive foot impairment is associated with the duration of the disease [3]. Early joint inflammation and pain may lead to compensatory changes in gait and load bearing in an effort to minimise pain, which results in abnormal loading pressures in the forefoot and forefoot joint damage [1]. Alteration in the pressure distribution across the forefoot during the gait cycle will lead to deformities that perpetuate joint erosion, limit daily activities and reduce the patient's quality of life [4,5].

Decreased plantar surface area resulting from the displacement or atrophy of the plantar fat pad will lead to increased plantar pressure [6]. Loading patterns across the foot may be measured using modern pedobarographic analysis to identify patients at risk of developing foot deformities and gait abnormalities. Abnormal peak pressures across the metatarsal heads of RA sufferers have been reported as 2-3 times higher than in healthy controls [7]. Although abnormal plantar pressures may result from foot deformities, muscle weakness and altered foot function during load bearing they may also influence the development of further forefoot deformities [1]. Plantar pressure analysis may be used to quantify both static and dynamic foot function while standing and walking, providing the clinician with information on the vertical component of the ground reaction forces and the load distribution across the plantar surface [8]. However, the value of pedobarographic analysis as a diagnostic tool for the screening of recently diagnosed RA patients remains uncertain [8,9]. The lack of uniformity in measures, the wide variety and sensitivity of pedobarographic instruments available (e.g. in-shoe or mat analysis), the large number of parameters that can be measured (manual versus automatic masking) the intrinsic complexity of the foot structure and variations in data extraction and the statistical analysis methodology, render a diagnosis uncertain [9]. Schmiegel et al. [10] found that pedobarography did not identify the regions of severe pain and concluded that such analyses had no clinical relevance. Such contradictory findings relating to foot pressure have resulted in uncertainty about its diagnostic value [9,10]. One key limitation of pedobarography is its failure to detect a patient's antalgic gait adaptation to minimising pressure that leads to pain [11].

Although there are many manufacturers of pedobarographic analysis devices and the validity and reliability of individual systems have been tested, there is little published information regarding the reproducibility of plantar pressure measurements between different devices (of the same or different manufacturers) or repeatability (of the same observer or for different observers).

Different pedobarographic systems give rise to varying resolutions, sensor types, calibration and processing regimens, sampling rates and ranges of detectable plantar pressure values [12,13]. Such variations cast doubt on the value pedobarography in the clinical diagnosis of foot pathologies [13]. In a recent review Deschamps et al. [8] suggest there is a paucity of robust guidelines as to the pressure quantities that should be analysed for the clinical diagnosis and treatment of foot abnormalities in RA.

The aim of this systematic review is to: a) assess the different instruments used to analyse plantar pressure; b) to report on the technical considerations associated with manual and automatic masking and c) to assess the validity together with the inter- and intra-observer reliability of pedobarographic analyses for identification of pathological profiles in patients suffering with RA.

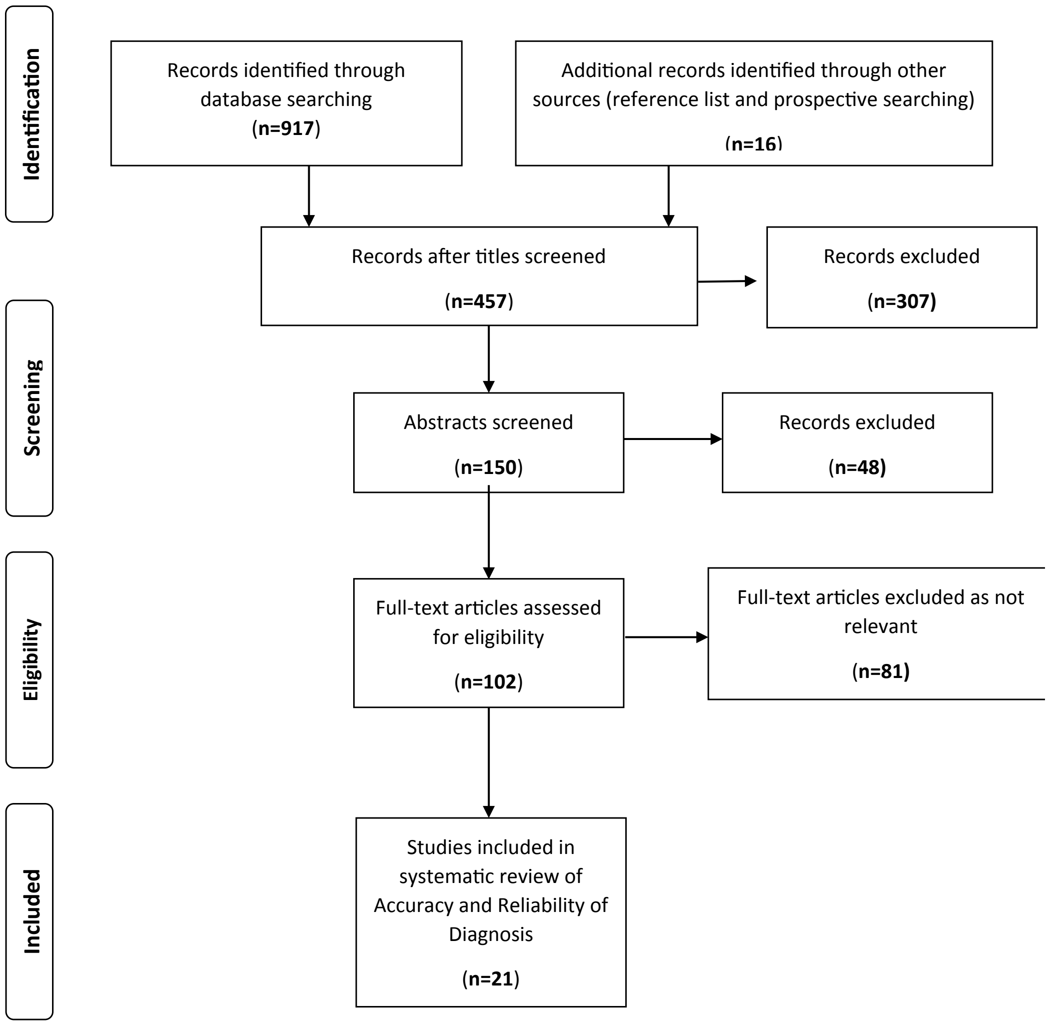
Method

Literature search

Following the PRISMA guidelines, a literature search was undertaken using a variety of computerised bibliographic databases including:

1. Web of Science
2. Scopus
3. EBSCO
4. Proquest
5. PubMed/Medline
6. CINAHL
7. Nursing & Allied Health Database

Additional papers were identified by manually searching the bibliographies of articles retrieved from the electronic search [14]. The combination of key words used in the literature search together with the number of papers identified in each search. A flow of inclusion and exclusion information through the different phases of assessing the collected papers (Appendix 1 and Figure 1).



Databases searched: Web of Science; Scopus; CINAHL; EBSCO; ProQuest, Nursing & Allied Health Database **Keywords/Phrases** used in search, singly or in combination: Inflammatory Arthritis; Rheumatoid

Arthritis (RA); Ankylosing Spondylitis; Psoriatic Arthritis; Gout and Gout Polymyalgia Rheumatica; Systemic Sclerosis and Systemic Lupus Erythematosus; in combination with Plantar Pressure

Figure 1: Flow of inclusion and exclusion information through the different phases of assessing the collected papers referring to plantar pressure measurement accuracy and reliability of diagnosis, using PRISMA flow diagram [14].

Quality appraisal of diagnostic reliability (QAREL) checklist

Quality appraisal tools are widely used as a measure of quality for studies of diagnostic reliability. The Quality Appraisal of Diagnostic Reliability (QAREL) developed by Lucas et al., consists of items that cover the spectrum of subjects, spectrum of examiners, examiner blinding, order effects of examination, suitability of the time interval among repeated measurements, appropriate test application and interpretation and appropriate statistical analysis [15].

Flow of inclusion and exclusion information through the different phases of assessing the collected papers referring to Plantar Pressure Measurement Accuracy and Reliability of Diagnosis, using PRISMA flow diagram (Figure 1) [14].

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Arthritis (RA); Ankylosing Spondylitis; Psoriatic Arthritis; Gout and Gout Polymyalgia Rheumatica; Systemic Sclerosis and Systemic Lupus Erythematosus; in combination with Plantar Pressure.

The QAREL test was developed because poor reliability devalues the accuracy of diagnostic tests and although other quality appraisal tools have been developed few have achieved widespread use [16-18]. The diversity of previous quality appraisal tools prompted Lucas et al. [10] to develop a unifying tool informed by existing tools. The QAREL checklist is presented (Appendix 2).

Reliability

Although reliability is a measure that clinicians and researchers perceive as important there is no definition of the level required for clinical acceptability [19]. Reliability is generally population specific and statistically significant levels of reliability may not translate into clinically acceptable levels and should be treated with caution. The reliability is:

1. Not an all-or-none phenomenon
2. Open to interpretation
3. Not the same as clinical acceptability
4. Population specific
5. Related to the variability in the group studied
6. Best estimated by more than one index

Reliability testing is usually performed to assess one of the following:

1. Instrumental reliability, i.e., the reliability of the measurement device
2. Rater reliability, i.e., the reliability of the researcher/observer/clinician administering the measurement device
3. Response reliability, i.e., the reliability/stability of the variable being measured

In the case of plantar pressure measurements, reliability measures must involve all three of the assessments above. However, for the pedobarographic studies reviewed there seems little consistency in how the authors estimate reliability from their data. This makes any comparisons between the pedobarographic instruments or methodology very difficult [19]. Typically the indices commonly used include:

1. Hypothesis tests for bias, e.g. paired t-test, analysis of variance
2. Correlation coefficients, e.g. Pearson's, intra-class correlation coefficients (ICC)
3. Standard error of measurement (SEM)
4. Coefficient of variation (CV)
5. Repeatability coefficient
6. Bland and Altman 95% limits of agreement

Of these measures, correlation coefficients were most commonly used in the studies selected from the literature search. However, the correlation only describes how two sets of data vary together, not the extent of agreement between them [19]. The use of correlation alone can be misleading and is not recommended when used in isolation. Although intra-class correlation coefficients (ICC) are a better measure of the degree of consistency and agreement across data, there is no acceptable level of reliability using ICC. In gait analysis reliability is assessed as: a) intra-trial e.g. repeated measurements in one patient on single day; b) inter-trial, e.g. between days and/or trials [20]. Reliability may also be tested against the same (intra-) or different (inter-) testers [20-22].

Validity

In a review of instruments measuring foot function, foot pain and foot related disability, van der Leeden et al. [23], assessed the quality of clinimetric studies and measurement properties using a checklist that defined different levels of evidence for reliability, validity, and responsiveness, that was dependent upon the quality of the methodology used in clinimetric studies. van der Leeden et al. [23] defined three different measures of validity:

1. Content validity; refers to the ability of an instrument to measure the concept intended.
2. Criterion validity; refers to the extent to which a measure relates to a gold standard.
3. Construct validity; measured the expected relationships with other measures within a subgroup of patients.

In pedobarographic studies content validity would measure the accuracy of the pressure detected by the instrument using a standardised bench test. As there are no gold standards for pedobarographic analyses at present and therefore criterion validity cannot be assessed. Construct validity would refer to the ability of the pedobarographic technique to identify specific clinical outcomes (e.g. forefoot deformities) particularly in the early onset of RA. Validity may also be tested for the same cohort of patients but with different pedobarographic measurement systems [12,23,24].

Pedobarographic techniques

The first plantar pressure instrument, based upon an air filled chamber was reported by Marey [25], before deformable material, that rendered an ink impression or optical methods, for recording data were developed. Currently a wide variety of systems are employed by manufacturers to measure, more reliably, plantar pressure evaluations. The most common examples of these use capacitive, resistive and piezo resistive sensors. When a force is applied to such electromechanical sensors they calculate the variations in the applied load by the proportional change in voltage, conductance or resistance [25,26]. These sensors can be arranged as a matrix array, measuring the differences in pressure across the plantar surface or as discrete sensors arranged in regions of interest (ROI). Pressure measurements can either be dynamic, which analyses the pressure across the sole of the foot during a few steps or static when the patient is standing erect but at ease. The plantar pressure systems can be in-shoe or across a mat. One advantage of in-shoe systems being they can be used to measure pressures outside the laboratory, in more realistic conditions that are collected and stored on a memory devise before computer analysis in the clinic or laboratory.

The division of the plantar surface into anatomical ROI's that provide more clinically relevant information is termed masking. The most frequent ROI are the heel, mid-foot and the forefoot. The forefoot, most often involved in RA, is usually subdivided into areas across one or multiple metatarsal heads, the hallux and the smaller toes. Masking can be achieved manually although this may require an a priori decision about the ROI, and may introduce inter-tester variability. Alternatively masking algorithms can be automatic with some pedobarographic systems. Masking algorithms may divide the foot into geometric areas, e.g. longitudinal bisection, or into specific anatomical ROI. Geometric division may not be appropriate in patients with foot deformities [27]. No standard or guidelines have been reported in the literature regarding the division of the foot into ROI and is dependent upon the objective of the study and the skill of the clinician/researcher. Deschamps et al. [8] suggests this precludes inter-study comparisons and may lead to opposing conclusions.

The analysis of ROI is dependent upon the objectives of the study or the pathophysiological problems with the foot. The pedobarographic ROI can be undertaken using; total area mapping (TAM) or local area mapping (LAM). To accomplish meaningful results using TAM of the foot the pedobarographic area is divided geometrically using algorithms such as those used by Cavanagh et al. [28] which divides the forefoot into three ROI; however, the correlation with the patient's anatomy could not be validated. Another mapping method originally described by Cooper and Dietz divides the foot into percentages of length and width [29]. Similar to the method of Cavanagh et al. [28] the correlation with the anatomy of the foot is often unclear which in turn limits clinical decision making. Free mapping allows clinicians to manually mask the ROI's and is claimed to be a more precise method than other TAM techniques especially in the presence of foot deformities or gait abnormalities [30]. However, Deschamps et al. [21] points out that the evidence in the literature to support the validity of this method is lacking. Manual mapping techniques risk inter-rater reliability issues when masking is a matter of interpretation.

Local are mapping divides the plantar area into smaller uniform ROI, the placements of which can be undertaken automatically or manually. Using identical ROI to make comparisons of pedobarographic quantities is therefore much easier. However, once again the lack of standardisation and potentially lower reliability limits the clinical relevance of local mapping, especially in the presence of foot deformities [21].

Integrated mapping, such as measuring peak plantar pressure at the same time as foot kinematics when walking, has been shown to be reliable despite the presence of foot deformities [31,32]. In a study involving 12 healthy children Stebbins et al. [32] demonstrated that automatic sub-area definition, based on marker placement, was reliable and that a comparison of the data revealed that the peak vertical force was a more reliable measure than peak pressure for each of the five sub-areas. Giacomozzi et al. [31] reported that the integrated system is effective when loading measurements in specific plantar foot subareas are required.

A detailed review of the physical quantities and diagnostic parameters used in pedobarographic measurements can be found in the review by Deschamps et al. [21]. A table of the variety of pedobarographic variables are presented (Appendix 3) [8].

Results

A search of the literature revealed twenty-four full text articles referring to the validity and reliability of pedobarographic analyses. Additional papers were identified by manually searching the bibliographies of articles retrieved from the electronic search. The combination of key words used in the literature search is detailed together with the number of papers identified in each search. A flow of inclusion and exclusion information through the different phases of assessing the collected papers (Appendix 1 and Figure 1).

Of the original 24 articles downloaded and vetted for analysis of validity and reliability, 5 were dismissed as they contained insufficient data on the validity and reliability of diagnostic pedobarographic measurements for patients with RA. Table 1 lists the articles in chronological order the measures of validity and reliability. Of the 20 articles selected 12 reported positive conclusions regarding validity and reliability of pedobarography. However, 3 articles reported negative conclusions 6, 9, 39 and 5 reported inconclusive results [1,4,5,12,13,20-22,24,26,27,33-39].

Table 1: The diagnostic reliability of plantar pressure measurement.

Study	Normal or RA or Gout	Published	n=	System	In-shoe or Mat	Testing	Validity	Measure	Repeatability	
									Inter-	Intra-
Tenten-Diepenmaat et al. [5]	RA	2016	45	Pedar-X	In	Adapting Orthotics	No data	PP	No data	$CI_{95\%}$ -11.39-16.24
								PTI		0.01-5.94
de Castro et al. [26]	N	2014	40	WalkinSense & Pedar	In	Bench test	*P*=<0.001[1]	PP	NA	ICC 0.999
						Dynamic	*P*=<0.001[1]	PP	ICC 0.979	ICC 0.972
								PTI	ICC 0.915	ICC 0.987
Choi et al. [9]	RA	2014	72	Gaitview	M	Static	*P*=0.136[2]	PP	No data	C 0.177-0.51[3]
						Dynamic	*P*=0.095[2]	PP	No data	C 0.135-0.49[3]
Scalpello et al. [1]	RA/N	2013	20	TekScan	M	Dynamic	P=0.000-0.011[4]	PP	No data	No data
Hafer et al. [12]	N	2013	22	E-Med, MatScan	M	Dynamic	No data	PP	ICC ≥ 0.70	ICC ≥ 0.90
Brenton-Rule et al. [33]	RA	2012	23	TekScan	M	Static	No data	PP	ICC 0.84-0.92	No data
Ellis et al. [27]	N	2011	10	E-Med-X	M	Static	59.4%-92.6%[5]	PP	No Data	No Data
						Dynamic	88.7%-98.9%[5]		No Data	No Data
Rome et al. [22]	G	2011	25	F-Scan	In	Dynamic	No Data	PP	No Data	C 0.92-0.97
								PTI		C 0.86-0.94
Chevalier et al. [24]	N	2010	21	F-Scan	In/M	Dynamic	No Data	PP	*P*=<0.01[6]	No data
Zammit et al. [38]	N	2010	30	TekScan	M	Dynamic	No Data	PP	ICC 0.920[7]	ICC 0.920[7]

Abbreviations: [1] Significant correlation between tests; [2] Significant differences between methods; [3] Correlation; [4] Pearson coefficient; [5] Percentage accuracy; [6] Significant differences between in-shoe and mat; [7] Mean; [8] RMSE (cm) for AM Cube; Medilogic; Novel and TekScan, respectively; [9] MTH2 and single masking; [10] Average measure estimate; [11] CR: Coefficient of Repeatability expressed as a percentage of the mean. These values were determined as an overall mean for the 10 areas of the plantar surface measured; [12] Mann Whitney *U* test after correction of PressureStat scores for background noise with median differences from 100 and -55kPa for midpoint and maximum readings *P*=0.0001 and 0.07; [13]Range of kappa values for the 4 observers. For forefoot regions observers had 62% complete agreement; [14]Mean ICC result taken from 3, 5, 7 measurements in 2 step protocol; [15] ICC (2,1) and (2,3), respectively calculated from the 18 trials of lateral-medial force index; [16] The mean after 3 walks; [17] No statistical analysis. PP: Peak Pressure; PTI: Force Time Interval; NA: Not Applicable; ICC: Interclass Correlation Coefficient; CR: Coefficient of Reliability. RA: Rheumatoid Arthritis; N: Normal; G: Gout; In: In Shoe; M: Mat

Discussion

The validity and reliability of pedobarographic measurements for use in patients with RA have been assessed by a number of studies although few have provided data for both measures. Foot related pathologies associated with RA include inflammation, structural damage and deformities which result in pain, aberrant loading patterns of the foot during weight bearing that limit daily activities and reduce a patient's quality of life [5]. Foot deformities are common in RA patient's involving 90% as the disease progresses. As deformity increases foot function diminishes [40-44]. Although pedobarography can be successfully employed to determine both static and dynamic plantar pressures for the determination of foot function, foot pain and disability its diagnostic value for RA has been called into question [6,9,39].

Of the papers reviewed that reported positively with respect to reliability Li et al. [45], reported good inter repeatability for peak pressures and peak force measurements across the plantar area. Although they found there was a biomechanical benefit for RA patients in reducing plantar pressures using orthotics, the effect was only seen in 10% of those tested [45]. Although van der Leeden et al. [36] found no significant difference between a one-step, two-step or three-step protocol they recommended a two-step measurement for the gait analysis of patients with chronic arthritis and determined the reproducibility of the E-Med system was good with and ICC of >0.80.

In a 2007 study using the in-shoe Pedar system Putti et al. [35] concluded the coefficients of repeatability were good (<0.10) and used the data (means and standard deviations) as a reference range in clinical practice. The ranges they suggest would help identify patients with borderline problems, although data on the success of diagnosing RA sufferers with borderline foot disorders was not reported. Schmiegel et al. [46] using the E-Med system reported that foot function decreased and foot related problems, such as pain, increased with changes in foot pressure patterns [46,47]. They suggested that pedobarographic measurements would be useful during the early stages of RA, before clinical examination indicates the need for more aggressive treatments, a point that is contrary to other researchers [6,9]. Putti et al. [35] who also measured the repeatability of the E-Med ST4 system found that the majority of the six parameters studied had a coefficient of repeatability of less than 10%. The highest regions of pressure found were beneath the second and third metatarsal heads and that peak pressure was the most relied upon parameter [35]. They confirmed their earlier findings with the Pedar system that data from their study could be used in orthopaedic clinics as part of the assessment of pathological conditions.

In their study of the repeatability of repeated pedobarographic measurements, Gurney et al. determined the intra-class correlation coefficients (ICC) and coefficients of variation (between days) were high enough to be used in comparative evaluations for clinical screening [20]. Although Vidmar and Novak found ICC ranged from 0.897 to 0.999 and claimed the F-Scan system to be highly reliable they still recommended that the average of several measurements should be undertaken [34]. In the 2011 study by Rome et al. [22] evaluating intra-tester reliability of manual masking with the F-Scan system, they found ICC's ranging from 0.86 to 0.94 for PTI's, but lower ICC's and SEM values for PP's under all of the toes, suggesting greater measurement errors in this region of the foot. The accuracy of auto-masking algorithms was studied by Ellis et al. [27] using the Novel ten-region auto-mask coupled with the E-Med system, reported that although the dynamic trials in normal feet were accurately identified the accuracy diminishes with static posture measurements. They also cautioned researchers/clinicians that care must be taken when determining plantar pressures from posture trials or when a patient's feet have a deformity. Static postural studies were undertaken by Brenton-Rule et al. using the TekScan MatScan system with elderly (60-80 years of age) RA patients [33]. The reproducibility measured by ICC's of 0.84-0.92 demonstrated good to excellent reliability. Although they measured between-session reliability, they gave no data for within-subject variability (Table 2).

The 2013 study by Hafer et al. [12] measured the intra-mat, intra manufacturer and inter-manufacturer reliability for four platforms; 2 E-Med-x plates and 2 MatScans; the results are given in Table 3. They reported the reliability results are consistent with symptom free healthy adults. Their reported intra-platform results indicated that plantar pressure measurements on both systems gave moderate to high reliability, results that are consistent with a number of other researchers [20,37,38]. The authors reported the inter-platform reliability exceeded a CR of 0.70 on most plantar pressure measures. They concluded that the data they collected from the same subject on different plantar pressure platforms were consistent and indicated that inter-manufacturer reliability was very similar (Table 3).

When comparing an in-shoe system (F-Scan system) with a pressure platform (MatScan system) Chevalier et al. found inconsistencies between the two systems and recommended that values obtained were not interchangeable [24]. However, when de Castro et al. compared the accuracy and reliability of the Walk-in-Sense system with the Pedar in-shoe equipment they reported the accuracy to give an ICC 0.999 [26]. The intra- and inter-trial peak pressure correlation coefficients were found to be 0.972 and 0.979 respectively. They concluded that the Walk-in-Sense platform produced good-to-excellent levels of accuracy and repeatability for pedobarographic variables during static-bench testing and dynamic gait analysis. They stated that a number of plantar pressure parameters could be used as standard values when using the Walk-in-Sense system.

Using the TekScan system Scalpello et al. [1] found that even in the early stages of RA, a statistically significant difference existed in peak pressure values between all regions of the plantar surface (with the exception of the hallux region) compared to healthy controls. The authors concluded that a medial shift in peak plantar pressures is likely to increase as RA progresses; results that are consistent with the work of Minns and Craxford [7]. Pedobarography they conclude could therefore be used to screen patients during the early onset of RA, to undertake precautionary measures to limit the damage that may ensue as the disease progresses. However, this is contrary to the findings of Otter et al., who reported no increase in plantar pressure between RA patients (diagnosis within 5-10years) and a control group; a point conceded by Scalpello et al. [1] who suggest that the increase in newer pedobarographic systems may account for the difference.

Centre of pressure variables have been used in gait analysis for many years [48]. The principle reason for determining this being the assumption that it is related to the magnitude of foot pronation and supination during walking. However, its reliability and validity have not been established. Although the results of a study by Cornwall and McPoil indicate that the lateral-medial area index and the lateral-medial force index have adequate between-trial reliability, neither of these centre of pressure variables should be used as a direct or indirect measure of frontal plane rear-foot eversion during the stance phase of walking [39]. Firth et al. [6] tested both the validity and reliability of the PressureStat system and found that the pressure outputs exceeded the range of the calibration curve where the largest deviation was in the lower ranges. With only fair to moderate intra- and inter-observer kappa values they concluded the pedobarographic testing of RA patients is inaccurate and imprecise. They suggest that other technology be used to determine plantar pressures in RA patients. Choi et al. [9] also found the diagnostic value of pedobarography low [9]. They determined the pressure values for each part of the foot gave a diagnostic correlation of 17.7% for static measurement and 13.5% for dynamic measurement. Graphic peak pressure gave a correlation of 41.7% for static measurement and a correlation of 31.3% for dynamic measurement. Contrary to the study of Choi et al. [9] and Quaney et al. [49] found low overall correlation between pressure values and symptomatic areas

Table 2: Quality appraisal of diagnostic reliability (QAREL) checklist.

Study	Normal or RA or Gout	Published	n=	System	In-shoe or Mat	Testing	Validity	Measure	Repeatability	
									Inter	Intra
Giacomozzi [13]	NA	2010	Bench	Various	In	Static	0.22-0.0.67 0.4-0.69 0.07-0.19 0.19-0.50[7]	PP	0.16-0.13 0.09-0.21 0.03-0.04 0.04-0.07[8]	No data
Deschamps et al. [21]	RA	2009	10	RScan	M	Dynamic	No Data	PP	ICC 0.79[9]	$CI_{95\%}$ 0.55-0.70
								PTI	ICC 0.68[9]	$CI_{95\%}$ 0.53-0.61
Vidmar and Novak [34]	RA	2009	12	F-Scan	In	Dynamic	No data	PP	No data	ICC 0.99[10]
Gurney et al. [20]	N	2008	9	E-Med	M	Dynamic	No data	PP PTI	No data	ICC 0.801 ICC 0.847
Putti et al. [35]	N	2008	53	E-Med	M	Dynamic	No data	PP PTI	No data	CR 5.84[11] CR 6.29[11]
Firth et al. [6]	RA	2007	10	Pressurestat and E-Med	M	Bench test Dynamic	3.71 and 1.80 [11]	PP	κ 0.21-0.59[13]	κ 0.57-0.33[13]
Putti et al. [4]	N	2007	53	Pedar	In	Dynamic	No data	PP PTI	No data	CR 5.42 CR 6.58
van der Leeden et al. [36]	RA	2004	20	E-Med	M	Dynamic	No data	PP	No data	ICC=0.856[14]
Cornwall and McPoil [39]	N	2003	105/30	E-Med	M	Dynamic/ Static	Not established	PP	ICC 0.215-0.486[15] 0.582-0.905[15]	No data
Hughes et al. [37]	N	1991	10	E-Med	M	Dynamic	No data	PP	No Data[16]	0.904[16]

Table 3: The inter- and intra-platform reliability of 4 different platform.

Test	Trial	Results
Intra-platform reliability		51 of 56 ICC values ≥ 9.0
Inter-platform reliability	10-trial mean	Inter-E-Med>0.7 for all parameters
		Inter-MatScan>0.7 for 31 of 56 parameters
	5-trial mean	Inter-E-Med>0.7 for all parameters
		Inter-MatScan ≥ 0.7 for 52 of 56 parameters
Inter-Manufacturer reliability		>0.7 for all parameters

In a recent review by Deschamps et al. [8], they determined that although selective sub-sampling (identifying regions of interest through masking techniques) was the more common method of determining foot abnormalities and facilitate clinical diagnoses, they found few standard practices or international guidelines. They ascribed this to technical limitations and the intrinsic complexity of the foot structure. Moreover they suggest that non-standard subjective practices limit comparative analysis between published studies and impede the development of multi-centre databases [8]. With no systematic methods of determining plantar pressure quantities and data extraction, the clinical use of pedobarography is limited especially in diseases such and RA [8]. Poor data reporting, small sample sizes and the heterogeneity of inflammatory arthritis limit the clinical interpretation of results. A standardised analytical approach is required to provide clinicians and researchers with objective evidence of foot function in people with RA 50.

The QAREL appraisal tool

The Quality Appraisal of Reliability Studies (QAREL) scores are presented in Table 2. The scale was used to determine the validity and the reliability of data from the 20 papers selected following the literature search for validity and reliability of pedobarography. The QAREL tool has an 11-item checklist that assess the external validity, internal validity, and statistical methods of reliability studies [50,51]. Each QAREL item is equally weighted and scored as 'Yes', 'No' or 'Unclear'. In the original development paper of the QAREL instrument Lucas et al. [15] did not quantify any scores that represents poor, moderate and good reliability. In previous systematic reviews of rater reliability employing QAREL researchers have used ≥ 50% or ≥ 60%, of affirmative answers [52-56]. Only two of the studies included in this review described any blinding of the test operator(s). The importance of blinding in reliability studies is described by Lucas et al. [15] and its importance is reflected as 5 of the 11 items on the QAREL checklist relate to blinding.

In this review the mean number of affirmative answers and standard deviation was 5.50 ± 1.53. For the papers reviewed in this study a score of ≥ 50% is not considered as high quality, as blinding is such an important element when taking pedobarographic measurements to reduce operator bias. With the adoption of ≥ 60% for affirmative answers, (the more common value in the literature) only 2 papers gained more than the 60%. Of those Choi et al. [9] reported that the diagnostic validity of pedobarography was low, while Ellis et al. [27] reported that the Novel auto-masking algorithm identifies most foot regions in normal feet, with the added corollary that such accuracy may be reduced by the presence of foot deformity. As a result of inadequate blinding, the results of this review, using the QAREL analysis of reliability, show there are strong evidence for poor to moderate intra- and inter-operator/platform reliability for pedobarography in normal subjects and RA patients. This is despite the statistical data (such as CR and ICC) reported in the studies reviewed that is considered moderate to good reliability.

Conclusion

Although the non-invasive pedobarographic screening of RA sufferers to analyse and characterise pathological foot deformities seems straightforward, the technology and methodology required for accurate and reliable clinically relevant results requires considerable expertise [8]. Two critical decisions are required before any pathomechanical modelling or functional interpretation regarding foot pathologies can be undertaken; a) the methodology necessary to the analyse plantar surface and b) the choice of plantar components to quantify [8]. The establishment of a standardised methodology for pedobarographic analysis has not been established and to date has not been reported. International guidelines to standardise pedobarographic methodology and data extraction is required to ensure parity between studies.

The literature concerning the validity and reliability of pedobarography in the screening for early onset foot deformities in RA patients has not been proven. Although the forefoot has been identified as a common area of the plantar surface where deformities occur in RA, there are very few studies that demonstrate any subtle changes in PP or PTI that could forecast forefoot deformities in asymptomatic RA patients.

The issue of automatic versus manual masking has been studied with varying results [22,27]. However, in the absence of a clinical gold standard the current approach in the choice of subsampling/masking remains arbitrary and prevents the comparison of published trials. The lack of standard practices may limit clinical use and compromise the interpretation of results (Appendix 1) [8].

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