A review of clinical studies on automatic ABI devices

by

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DOPPLEX ABILITY: UNIQUE KEY FEATURES

1. A SUPERIOR BLOOD PRESSURE MEASUREMENT PRINCIPLE

Most automated blood pressure devices work on the principle of oscillometry: arterial oscillations, caused by the contraction of the heart, are detected within the blood pressure cuff. Whilst this technique works satisfactorily for measuring blood pressure in the arm, it is often not sensitive enough to detect the blood pressure at the ankle, particularly in patients who have peripheral arterial disease (see study 4).

The Dopplex Ability utilises a different measurement principle, known as volume plethysmography to measure the blood pressures in all four limbs simultaneously. This method does not depend upon arterial oscillations and is far more sensitive for detecting lower blood pressures, particularly in the ankle or foot and hence is a more accurate way of detecting and quantifying PAD.

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2. ELIMINATES THE NEED TO REST PATIENTS PRIOR TO THE ABI MEASUREMENT PROCEDURE.

The ABI aims to assess how blood pressure in the upper limbs differs to blood pressure in the lower limbs to provide an indication of whether the arterial status of the legs may be compromised. However, this assessment can be affected by the fact that blood pressure constantly fluctuates as a result of factors such as stress, activity and body position. Resting the patient in the supine position prior to measuring the ABI aims to allow these fluctuations to settle and minimise their effect on the ABI. This is why automatic ABI systems that only use two cuffs require the patient to be rested.

The Dopplex Ability measures the systolic pressures in all four limbs simultaneously in just three minutes, meaning that blood pressure fluctuation over time will not affect the attained ratio of the lower limb pressure compared to the upper limb pressure. This therefore negates the need for a rest period prior to the measurement procedure and makes ABI measurement much more amenable for use in all clinical settings.

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3. UNIQUE DUAL CHAMBER CUFF

The Dopplex Ability cuffs have a unique dual-chamber design. An upper “occlusion” chamber occludes the blood flow and a lower “sense” chamber detects returning blood flow as the upper occlusion chamber slowly deflates. This design reduces the potential for interference in the detection of returning blood flow resulting in reduced measurement errors and highly accurate results.

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4. PROVIDES A SECOND LINE OF ARTERIAL ASSESSMENT

A well recognised limitation of the ABI concerns the fact that it becomes inaccurate or non-diagnostic in the presence of arterial calcification (which is associated with advancing age, hypertension, diabetes mellitus and chronic kidney disease). The Dopplex Ability provides a print-out of pulse volume recordings for each leg which provides a second line of investigation that not only highlight when this has occurred, but also provide qualitative pictorial information with regard to the arterial status of the limb. Use of pulse volume recordings is recommended by both the European Society of Cardiology (Tendera et al., 2011) and the American College of Cardiology/American Heart Association (Anderson et al., 2013) as a second level assessment tool for patients with suspected PAD.

DOPPLEX ABILITY: CLINICAL STUDIES

Clinical evidence demonstrating the validity and accuracy of the Dopplex Ability comes from seven robust clinical research trials:

Study 1: A comparison between Dopplex Ability and the Doppler method for obtaining ankle brachial pressures.

Authors: Lewis et al. (2010)

Study Aim: To determine the agreement between rested and unrested Dopplex Ability ABI measurement with ABI attained by the traditional Doppler ultrasound method.

Study Type: Randomised cross-over trial comparing (i) Ability ABIs measured after a 10 minute rest period, (ii) Ability ABIs measured with no prior rest period and (iii) Doppler ABI measurement.

Methodology: 200 subjects referred to a vascular laboratory for investigation of possible claudication or absent pedal pulses underwent ABI measurement using the traditional Doppler method and the Dopplex Ability. Each subject was randomised to sequence A or sequence B.

The Dopplex Ability was applied and operated according to manufacturer's instructions by a single clinician, who was blinded to its results. Doppler ultrasound ABI measurement was undertaken by the same clinician according to the Ankle Brachial Pressure Index standard operating procedure specified by the Scottish Diabetic Research Network (2010).

Test modality	**Reference Standard: Doppler ABI<0.9**		
	Sensitivity	Specificity	Accuracy
Dopplx Ability ABI (un-rested)	79%	91%	85%

Key Results:

95% limits of agreement of Ability with Doppler method	Ability Failed Measurement Rate	Ability correlation with Doppler
Rested: ±0.22	Rested: 3.6%	Rested: Pearson's r =0.89
Unrested: ±0.21	Unrested: 1.2%	Unrested: Pearson's r = 0.89

Test Time

	Ability Unrested	**Ability Rested***	**Doppler†**
Mean time	7.1 min	4.6 min	16.5 min

*Times do not include fitting of cuffs

†Excludes resting times.

Conclusions and Clinical Significance:

- This study demonstrated that both the unrested Ability ABI and rested Ability ABI correlate well with Doppler ABI hence providing evidence that (i) the automated device functions with a high degree of accuracy and (ii) there is no need to rest patients prior to its use.
- Use of the Dopplex Ability can result in a considerable reduction in the time needed to undertake ABI measurement hence making it far more amenable for use in all clinical settings.

Study 2: A comparison between Doppler and a new automatic method for obtaining ABI

Authors: Lewis et al. (2012)

Study Aim: To determine the performance of the Dopplex Ability on patients with leg ulcers or suspected PAD via assessment of its agreement with Doppler ABI.

Study Type: Observational

Methodology: 149 limbs of subjects, which were recruited opportunistically as they presented at clinics, underwent ABI measurement using the Dopplex Ability first and then Doppler after a 15 minute rest period.

Key Results:

Test modality	**Reference Standard: Doppler ABI**		
	Sensitivity	Specificity	Accuracy
Dopplex Ability ABI (<0.8) (<0.9)	 82% 78%	 97% 93%	 94% 88%

95% limits of agreement of Ability with Doppler method: ±0.24

ABI range measured by the Ability: 0.24 – 1.37

Correlation with Doppler ABI: Pearson's $r = 0.86$, $p < 0.05$

Conclusions and Clinical Significance

- Accurate ABI measurement is essential for patients with suspected PAD and also for patients with lower limb wounds as it not only assists in determining wound aetiology but also can be used to determine if compression therapy is suitable.
- This study demonstrates that the Dopplex Ability has very good agreement with Doppler ABI in such a population

Study 3: The utility of pulse volume waveforms in the identification of lower limb arterial insufficiency

Authors: Davies et al. (2014)

Study Aim: to determine the utility of pulse volume recording (PVR) analysis for identification of lower limb arterial insufficiency in the presence of arterial calcification.

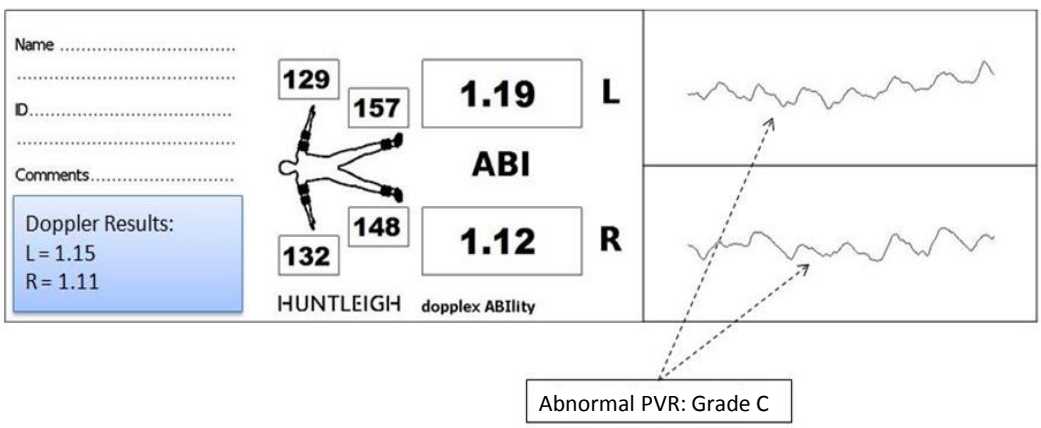
Study Type: Observational

Methodology: Individuals (n = 1101) registered at a Welsh general practice, without any known cardiovascular disease or diabetes, were invited to undergo cardiovascular risk assessment involving ABI measurement. The ABI was measured using both the Dopplex Ability (which also provided PVRs for analysis) and the traditional Doppler ultrasound method.

Key Results:

Eight percent of participants (30/368) had an ankle brachial index ≥1.3, suggesting possible arterial calcification; consideration of the pulse volume waveform in these cases identified possible mild peripheral arterial disease in three cases (10%).

Furthermore, in one case, the ankle brachial indices were within the normal range, but the pulse volume recordings suggested a moderate degree of arterial insufficiency (see figure below); **this participant was subsequently diagnosed with bilateral superficial femoral artery stenoses and treated accordingly.**



For more information on interpretation of the PVR waveforms, refer to the PVR application note available from: www.huntleigh-diagnostics.co.uk

Conclusions and Clinical Significance:

- This study highlights the shortcomings of the ABI as a single diagnostic tool and demonstrates the need for a secondary mode of lower limb arterial assessment that is easy for non-specialist practitioners to use.
- The prevalence of an elevated ABI (≥1.3) within this study was relatively high even in a population in which diabetics were excluded. Furthermore, this study also highlights that *the ABIs of patients with PAD can sometimes be artefactually raised to within normal limits*. **In such cases, simple analysis of PVRs is a useful adjunct for the identification of patients who require further vascular investigation.**

Study 4: A comparison of ABI measured with automated systems and conventional Doppler for identifying PAD.

Authors: Aslam & Shaw (2015)

Study Aim: Compare Doppler ABI with (i) an oscillometric automated ABI device and (ii) a plethysmographic automated ABI device.

Study Type: Observational

Methodology: 49 patients referred to a vascular laboratory for lower limb arterial assessment underwent ABI measurement using (i) an automated system based on oscillometry, (ii) an automated system based on volume plethysmography and (iii) a handheld Doppler which was considered the 'gold standard' of the study.

Key Results:

Test modality	Reference Standard: Doppler ABI			
	Sensitivity	Specificity	95% limits of agreement	Correlation (Pearson's r)
Oscillometric ABI (MESI) (n = 71 legs)	50%	95%	±0.43	0.38 ($p<0.05$)
Plethysmographic ABI (Dopplex Ability) (n = 73 legs)	93%	95%	±0.24	0.86 ($p<0.05$)

Conclusions and Clinical Significance:

- **The Oscillometric device**: had poor correlation with Doppler and sensitivity for detecting PAD. It also had difficulty measuring ABIs below 0.8 and hence could not be reliably used to provide an accurate ABI.
- **The Plethysmographic device:** had comparable results with Doppler and very good sensitivity and specificity.
- This study therefore provides evidence that the plethysmographic device used (Dopplex Ability) has a high level of accuracy which gives it the potential to be used in the measurement of ABI in place of Doppler.
- The Dopplex Ability can be used by community based nurses or GPs for ABI measurements to streamline the referral process to secondary care.

Study 5: Non-invasive assessment of peripheral arterial disease: Automated ankle brachial index measurement and pulse volume analysis compared to duplex scan

Authors: Lewis et al. (2016)

Study Aim: To individually and cumulatively compare sensitivity and specificity of the (1) ankle brachial index and (2) pulse volume waveform analysis recorded by the same automated device, with the presence or absence of peripheral arterial disease being verified by ultrasound duplex scan.

Study Type: Observational

Methodology: Patients (n=205) referred for lower limb arterial assessment underwent ankle brachial index measurement and pulse volume waveform recording using volume plethysmography, followed by ultrasound duplex scan. The presence of peripheral arterial disease was recorded if ankle brachial index <0.9; pulse volume waveform was graded as 2, 3 or 4; or if haemodynamically significant stenosis >50% was evident with ultrasound duplex scan. Outcome measure was agreement between the measured ankle brachial index and interpretation of pulse volume waveform for peripheral arterial disease diagnosis, using ultrasound duplex scan as the reference standard.

Key Results: 189 subjects (65% male, mean age: 67±12, 26% diabetic) completed the study, 36% of subjects were found to have PAD according to Duplex ultrasound results.

Test modality	**Reference Standard: Duplex ultrasound scan**		
	Sensitivity	Specificity	Accuracy
Dopplex Ability ABI (<0.9)	79%	91%	88%
Qualitative analysis of Dopplex Ability PVR	97%	81%	85%
Combined (ABI ≤0.9 and/or PVR grade B,C or D)	100%	76%	85%

Ability Failed Measurement Rate: 1.5% ABI range measured by the Ability: 0.29-1.57

Conclusions and Clinical Significance:

- This study demonstrates that both the Dopplex Ability ABI and qualitative analysis of pulse volume recordings offer a high degree of accuracy for the diagnosis of PAD (as compared to the gold standard of Duplex ultrasound scan).
- Combining these two diagnostic modalities within one device provided a highly accurate method of ruling out peripheral arterial disease, which could be utilised in primary care to safely reduce unnecessary secondary care referrals.
- The Dopplex Ability ABI had a lesser degree of sensitivity than PVR analysis (85% vs. 97%); this can be attributed to the fact that over a quarter of the study population had diabetes which meant an increased likelihood of the presence of arterial calcinosis which can falsely elevate ABIs making them non-diagnostic.
- ABIs measured ranged from 0.29 – 1.57 indicating good performance at the extremes of the ABI spectrum.

Study 6: An investigation between oscillometry and plethysmography based devices in the measurement of ABPI in comparison to the Doppler gold standard.

Authors: Aslam (2016)

Study Aim: Compare Doppler ABI with (i) an oscillometric automated ABI device and (ii) a plethysmographic automated ABI device for identifying peripheral arterial disease.

Study Type: Observational

Methodology: 26 patients referred to a London vascular laboratory for lower limb arterial assessment underwent ABI measurement using (i) an automated system based on oscillometry, (ii) an automated system based on volume plethysmography and (iii) a handheld Doppler which was considered the 'gold standard' of the study.

Key Results:

Test modality	Reference Standard: Doppler ABI		
	95% limits of agreement	Bias	Correlation (Pearson's r)
Oscillometric ABI (Watch BP Office Device: Microlife)	±0.43	-0.08	0.61 ($p<0.05$)
Plethysmographic ABI (Dopplex Ability)	±0.2	-0.015	0.9 ($p<0.05$)

Conclusions and Clinical Significance:

The oscillometric device had difficulty measuring ABPIs below 0.8 and could not be used to reliably provide an ABPI prior to compression bandaging and treatment planning. Both systems are fast and easy to use but the accuracy of the plethysmographic device gives it the potential to be used in the measurement of the ABI in place of Doppler prior to compression bandaging

Study 7: Automated plethysmographic measurement of the ankle-brachial index: a comparison with the Doppler ultrasound method

Authors: Davies and Williams (2016)

Study Aim: To determine the agreement between Doppler ABI and Dopplex Ability ABI

Study Type: Observational

Methodology: 380 subjects with cardiovascular risk factors but no pre-identified cardiovascular disease underwent ABI measurement firstly using the automated Dopplex Ability and secondly using the traditional Doppler method (undertaken according to AHA recommended procedure – Aboyans et al., 2012). All measurements were undertaken by the same clinician, who was blinded to the results of the Dopplex Ability.

Key Results:

Test modality	**Reference Standard: Doppler ABI<0.9**		
	Sensitivity	Specificity	Accuracy
Dopplex Ability ABI	70%	96%	94%

Note: Lower sensitivity was attributed to the fact that 44% of PAD cases within the sample were mild (ABI 0.86-0.9), hence if the Dopplex Ability returned a result that was only 0.01-0.04 units higher than Doppler, then a false negative result was recorded.

Test Time

Method	**Time**	
Doppler ABI (including 10 minute rest period)	17.45 minutes (±1.08)	P < 0.01* Therefore ABI measurement using the Dopplex Ability is significantly faster than ABI measurement using the traditional Doppler method
Ability ABI (including application of cuffs)	7.55 minutes (±1.5)	

* Wilcoxon signed rank test

95% limits of agreement of Ability with Doppler method: ±0.2
Ability Failed Measurement Rate: 2.9%
ABI range measured by the Ability: 0.44 - 1.51
Correlation with Doppler ABI: Spearman's r = 0.72, p < 0.01

Conclusions and Clinical Significance:

- This large study demonstrated that the Ability can be accurately used for the purpose of PAD identification and cardiovascular disease screening in a general practice setting.
- ABI measurement using the Dopplex Ability is significantly faster than Doppler ABI measurement hence making it far more amenable for use in all clinical settings.

AUTOMATED ABI DEVICES: OSCILLOMETRY vs. PLETHYSMOGRAPHY

Current research evidence relating to four commercially available, automated, oscillometric ABI devices is summarised in the table opposite.

Points of note in relation to oscillometric devices:

High failed measurement rates in populations likely to have PAD.

- The failed measurement rate is high for the BOSO device (24% Diehm et al., 2009). Wohlfahrt et al. (2011) reported a lower failed measurement rate of 9.3% for the BOSO device but notably only 1.7% of the study population were found to have PAD. He concluded **"The BOSO ABI device cannot be used interchangeably for standard Doppler ABI measurement in diagnosing PAD."**

Lower correlation with Doppler ABI in populations likely to have PAD.

- Sinski et al.'s (2013) study involving Microlife's Watch BP automated ABI device reported a sensitivity of only 46% for detection of PAD in a population where 35% were confirmed to have the disease. He concluded that **"the Watch BP Office ABI system should be used with caution for PAD detection and screening in patients with CAD, and this system should not replace the Doppler method in populations at high risk of cardiovascular disease."**

- Several studies emphasise a systematic tendency of oscillometric devices to over-estimate the ankle pressure in patients with low lower limb systolic pressures (Korno et al., 2009) which may partly explain why lesser correlations are detected when study populations have greater proportions of participants with PAD.

- The study by Verberk et al. (2012) conducted a systematic review and meta-analysis of 25 studies with 4186 subjects, assessing the usefulness of automated oscillometric devices for ABI and PAD estimation compared with the conventional Doppler ultrasound method. The 25 studies involved the use of 20 different oscillometric devices (only 5 of which were designed specifically for ABI measurements whilst the remainder were devices originally intended for determination of brachial systolic pressures only). **Cumulatively, the sensitivity for PAD diagnosis was only 69%** and specificity 96%. The authors concluded that **oscillometric devices become less accurate in patients with lower ankle pressures.**

The Dopplex Ability in comparison, has been shown to accurately measure ABIs ranging from 0.29 – 1.57. Failed measurement rates are much lower than for oscillometric devices even when the study populations contained high proportions of PAD participants: 1.2% (Lewis et al., 2010), 1.5% (Lewis et al., 2016), and 3.2% (Davies et al., 2014). The use of volume plethysmography technology is far more sensitive for detecting lower systolic blood pressures.

Test Device	Research Evidence											
	Author/Date	Study details (type/sample size)	Study Results									
			Sens	Spec	PPV	NPV	Acc	95% Limits of agreement	Correlation coefficient	Failed Measurement rate	ABI range measured	Study Strengths/ Weaknesses
Dopplex Ability (Huntleigh Healthcare)	Lewis et al. (2010)	Reference Standard = Doppler ABI 200 subjects referred to a vascular lab with suspected PAD	79%	91%	NR	NR	85%	Rested: ±0.22 Unrested: ±0.21	0.89	1.2%	NR	Strength: Robust study methodology Weakness: Small sample size.
	Lewis et al. (2012)	Reference Standard = Doppler ABI 149 limbs of patients with leg ulcers or suspected PAD	82%	97%	NR	NR	94%	±0.24	0.86	NR	0.24 – 1.37	Weakness: Small sample size.
	Aslam & Shaw (2015)	Reference Standard = Doppler ABI 49 subjects referred to vascular laboratory for assessment Mean age: 58	93%	95%	NR	NR	NR	±0.24	0.86	NR	NR	Weakness: Small sample size.
	Lewis et al. (2016)	Reference Standard = Duplex ultrasound scan 205 subjects with suspected PAD, Mean Age: 67, 26% diabetic	79%	91%	76%	92%	88%	NR	NR	1.5%	0.29 – 1.57	Strength: Compared test device to a superior diagnostic modality (Duplex Ultrasound scan) Large sample size with 36% having PAD.
		Qualitative analysis of PVRs	97%	81%	65%	99%	85%	NA	NA	NA	NA	Provides second line of arterial assessment (PVR analysis) in addition to ABI.
		Combined ABI & PVR analysis	100 %	76%	71%	100%	85%	NA	NA	NA		
	Davies & Williams (2016)	Reference Standard = Doppler ABI 724 limbs, Age 36 -87	70%	96%	52%	98%	94%	± 0.2	0.72	3.9%	0.47 – 1.49	Strength: Large sample size Weakness: Small proportion (5.7%) of sample had PAD.
	Aslam (2016)	Reference Standard = Doppler ABI 26 subjects referred to vascular laboratory for assessment Mean age: 58	NR	NR	NR	NR	NR	± 0.2	0.9	NR	NR	Weakness: Small sample size. Proportion of subjects found to have had PAD not reported.

Test Device	Research Evidence											
	Author/Date	Study details (type/sample size)	Study Results									
			Sens	Spec	PPV	NPV	Acc	95% Limits of agreement	Correlation coefficient	Failed Measurement rate	ABI range measured	Study Strengths/ Weaknesses
Boso ABI system (BOSO)	Diehm et al. (2009)	**Reference Standard = Doppler ABI** 100 limbs with chronic symptomatic PAD	NR	NR	NR	NR	NR	± 0.22	0.77	24%	Unable to determine.	**Weakness:** Sample contained only diseased participants. Small sample size.
Boso ABI system (BOSO) contd.	Wohlfahrt et al. (2011)	**Reference Standard = Doppler ABI** 930 subjects, aged >25 years	77%	98%	33%	100%	NR	± 0.2	0.29	9.3% Boso	0.7 – 1.35 approx.(mean of 2 measurements estimated by visual inspection of Bland-Altman plot)	**Strength:** Large sample size **Weakness:** Non-standard Doppler ABI methodology utilised. Only 1.7% of study population had PAD according to Doppler ABI.
Watch BP office device (Microlife)	Kollias et al. (2011)	**Reference Standard = Doppler ABI** 93 subjects attending diabetic or hypertension outpatient clinic	83%	97%	NR	NR	95%	NR	0.8	1.6%	0.55 – 1.4 (approx. – estimated by visual inspection of Bland-Altman plot)	**Weakness:** Small sample size. Only 15% of subjects had PAD according to Doppler ABI
	Sinski et al. (2013)	**Reference Standard = Doppler ABI** 80 subjects with confirmed coronary artery disease	46%	98%	93%	77%	NR	± 0.43	NR	2.5%	NR	**Strength:** Robust study methodology **Weakness:** Small sample size.
	Rodriques Roca et al. (2014)	**Reference Standard = Doppler ABI** 322 subjects without known PAD in primary care (mean age 47)	NR	NR	NR	NR	NR	±0.19	0.7	NR	0.9-1.6	**Strength:** Large sample size **Weakness:** Sample contained no cases of PAD (according to Doppler ABI).
	Aslam (2016)	**Reference Standard = Doppler ABI** 26 subjects referred to vascular laboratory for assessment Mean age: 58	NR	NR	NR	NR	NR	±0.43	0.61	NR	NR	**Weakness:** Small sample size. Proportion of subjects found to have had PAD not reported.
Vantage ABI (Wallach)	**No published research available**											
IHealth Cardiolab	**No published research available**											

NR = not reported, NA = not applicable

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