Helping Reduce Amputations
New PAD Test Better than ABI in Diabetics

Diabetic patients with peripheral artery disease (PAD) account for up to 90% of the 150,000 non-traumatic amputations performed each year in the US. Finding and treating these patient's PAD earlier could help reduce amputations. However, the current most recommended test for finding PAD, the ankle-brachial index (ABI), has significant limitations in patients with calcified arteries, which includes many diabetics. Newman Medical has developed a more accurate and easier test for these patients based on computerized analysis of the digitized pulse volume recording (PVR) waveform at the ankle.

Background – The Amputation Crisis:

There are 150,000 non-traumatic amputations per year in the US – about 400 every day. The rate of amputations among diabetics grew at rate of 50% from 2009 to 2015.[1] This "amputation crisis" has led several leading societies and organizations to call for more focus on preventing amputations:

- A recent policy statement from the American Heart Association calls for "Reducing Nontraumatic Lower-Extremity Amputations by 20% by 2030: Time to Get to Our Feet".
- Four leading medical societies (Association of Black Cardiologists, Society for Cardiovascular Angiography & Interventions, Society of Interventional Radiology, and the Society of Vascular Surgery) have joined together to as the PAD Pulse Alliance to help people **Get a Pulse on PAD.**[2]
- The American Diabetes Association has called a yearly vascular screening of the lower limbs a "standard of care"[3].

Early diagnosis and treatment of PAD is effective at reducing amputations. However, PAD is often not recognized by patients or their health providers because it comes on gradually and the symptoms, if present, are often mistaken for arthritis or "old age". To diagnose PAD in its early stages the most common recommendation is the ankle-brachial index (ABI) that compares the ratio of the blood pressure at the ankle to that of the brachial artery. However, many diabetics have calcified arteries, and this leads to several issues with the standard ABI:

Amputation Resulting from PAD

- More feared than death by patients[4].
- Increases risk of depression and mobility loss.
- Disproportionately affects people of color (up to 4x more common).
- 3-year mortality risk jumps to 71%.

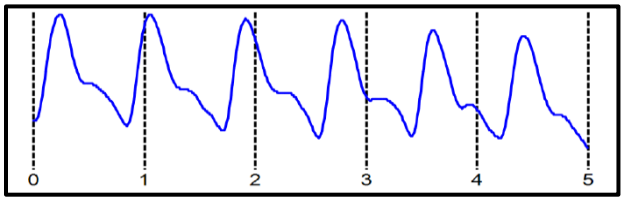
Standard Doppler-Based ABI Limitations:

- The accuracy of the ABI is significantly reduced in diabetics with calcified arteries. Calcification artificially raises the pressure taken at the ankle and thus causes an error in the ABI and underestimates the severity of PAD.
- This holds true regardless of the method used to measure blood pressure, whether it be Doppler, photoplethysmography (PPG), secondary cuffs, or oscillometric techniques.
- Recent studies by Aburama in a major accredited vascular laboratory[5] indicated that because of arterial calcification, the accuracy of the ABI in diabetics was only 66%. Even the toe-brachial index (TBI), which is often recommended if the ABI seems elevated, was found to be only 74% accurate for diabetics.

Overcoming Doppler-Based ABI Issues with the ABI-Q Exam:

We have addressed Doppler-based ABI issues and have developed what we believe is a better test (called the ABI-Q) for finding PAD in these diabetic patients with calcified arteries. As shown below, it is more accurate, especially in diabetics, and is easier to perform with fast results. The new ABI-Q exam is based on the pulse volume recording (PVR) at the ankle. PVR exams have been used in the vascular laboratory for many years, but their use has been limited by the necessity of the test interpreter subjectively analyzing the PVR waveform.

Considering the accuracy and ease of the PVR exam but concerned about the subjective nature of PVR waveform analysis, we have developed a test for analyzing the PVR waveform and providing a graded quantitative result. Our simpleABI systems digitize the PVR, allowing a detailed computerized analysis of the waveform and examining some of the key parameters shown on the PVR waveform below.



Typical PVR waveform. Key parameters include sharpness of peak, amplitude, presence of dicrotic notch

We initially analyzed studies from 120 patients (240 limbs), including 32 limbs with PAD. A proprietary algorithm was developed from this analysis resulting in assigning a quantitative value to the waveform that we have called the ABI-Q. To ease comparisons with standard ABIs we assigned values of the ABI-Q to be similar to standard ABI values: ABI-Q <0.90 implies increased risk of PAD, 0.91 to 0.99 is borderline, and >1.00 implies decreasing risk of PAD.

Recent improvements using simple exercises:

More recently, we have had the opportunity to analyze ABI-Q data from 34 patients (67 limbs, 11 with PAD) with the ABI-Q value measured after the patient performed 50 ankle flexions (pointing toes alternatively towards toes and ankles) while prone on the exam table. Even this relatively easy exercise has the effect of increasing the accuracy and sensitivity of the exam since as noted by Raines[6] the PVR amplitude increases after exercise for normal patients but decreases in the presence of PAD.

To determine the accuracy of this test we compared it to a finding of PAD as determined by the analysis of the PVR waveform by an experienced examiner. The examiner was blinded to the ABI-Q results. Recent studies by Lewis have shown that a PVR waveform study properly analyzed and graded by an experienced examiner can accurately determine the presence of PAD when compared to other modern diagnostic techniques. In one study[7], graded PVR waveforms were compared to ultrasound duplex imaging of the leg arteries and resulted in an agreement of 97%.

Using an ABI-Q value of less than 0.9 as indicative of PAD, this analysis yielded these results for the ABI-Q exam:

- Overall accuracy (Total True Positive + Total True Negative)/ Total) of the ABI-Q after exercise was determined to be 90%.
- Sensitivity was 91%
- Specificity 89%.

ABI-Q with Exercise compared to Standard ABI

- **Not affected by incompressible arteries – especially important for many diabetics.**
- **More accurate than standard ABI in diabetics (90% vs 66%).**
- **Much easier and faster procedure – wrap/inflate ankle cuffs – results immediately calculated.**
- **The faster, more comfortable, and less complex ABI-Q exam can improve the patient experience.**

The ABI-Q Advantage for Diabetic Care: A More Precise Approach to PAD Detection

Traditional Doppler ABI struggles with calcified arteries common in diabetics, leading to missed PAD diagnoses. ABI-Q with exercise offers a more precise approach:

- **Overcomes Calcification:** Unlike traditional Doppler-based ABI exams, ABI-Q uses PVR waveforms unaffected by calcification, providing a clearer picture of blood flow.
- **Earlier Intervention:** Accurate PAD detection allows for earlier treatment, reducing amputation risk, heart attack/stroke risk, and mobility limitations.
- **User-Friendly, Quick Exams:** The simpler ABI-Q exam is easy to learn and fast, streamlining workflow and improving patient throughput.
- **Enhanced Accuracy with Minimal Effort**: A simple ankle flexion exercise significantly improves test accuracy while requiring minimal patient exertion.

Conclusions:

By addressing the limitations of traditional ABI testing on diabetics, ABI-Q offers a more accurate, objective, and patient-friendly approach to PAD detection. This empowers physicians with a faster, easier-to-use test that delivers reliable results. ABI-Q's ability to overcome calcification, a common challenge in diabetic patients, allows for earlier intervention and improved patient outcomes. This translates to a significant reduction in amputation risk, heart attack/stroke risk, and mobility limitations for diabetic patients.

Newman Medical: Committed to Advancing Diabetic Care:

Newman Medical is dedicated to developing innovative solutions that improve the lives of diabetic patients, especially reducing amputations. ABI-Q with exercise exemplifies this commitment by providing a more accurate and accessible method for early detection of PAD, ultimately contributing to improved patient outcomes.

1. Creager MA, Matsushita K, Arya S, Beckman JA, Duval S, Goodney PP, Gutierrez JAT, Kaufman JA, Joynt Maddox KE, Pollak AW, Pradhan AD, Whitsel LP; on behalf of the American Heart Association Advocacy Coordinating Committee. Reducing nontraumatic lower-extremity amputations by 20% by 2030: time to get to our feet: a policy statement from the American Heart Association. *Circulation*. 2021;143:e875–e891. doi: 10.1161/CIR.0000000000000967
2. Gornik HL, Aronow HD, Goodney PP, Arya S, Brewster LP, Byrd L, Chandra V, Drachman DE, Eaves JM, Ehrman JK, Evans JN, Getchius TSD, Gutiérrez JA, Hawkins BM, Hess CN, Ho KJ, Jones WS, Kim ESH, Kinlay S, Kirksey L, Kohlman-Trigoboff D, Long CA, Pollak AW, Sabri SS, Sadwin LB, Secemsky EA, Serhal M, Shishehbor MH, Treat-Jacobson D, Wilkins LR. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS guideline for the management of lower extremity peripheral artery disease: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2024:149
3. *Diabetes Care* 2024;47(Supplement_1):S231–S243
4. Thorud, Jakob, Mortality and Lower Extremity Amputation: What We Know Now, Podiatry today, April 2024
5. AbuRahma, Ali F, Clinical analysis and limitations of resting ankle-brachial index in the diagnosis of symptomatic peripheral arterial disease patients and the role of diabetes mellitus and chronic kidney disease, Journal of Vascular Surgery, Vol 71, No 3, March 2020
6. Raines, Jeffrey K., the Pulse Volume Recorder in the Diagnosis of Peripheral Arterial Disease, in Current Noninvasive Vascular Diagnosis, Aburama, Ali, PSG Publishing Company 1988
7. Lewis, J. Automated ankle brachial index measurement and pulse volume analysis compared to duplex scan, SAGE Open Medicine, 2016; Vol.4,1- v 71, No 9