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Second Toe Systolic Pressure Measurements are Valid Substitutes for First Toe Systolic Pressure Measurements in Diabetic Patients: A Prospective Study ☆

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WHAT THIS PAPER ADDS

Toe systolic pressure is a simple, yet effective component of standard vascular and diabetic foot assessment. Until now, clinicians have been unable to measure systolic toe pressure on the second to fifth toes given a lack of evidence. In this study, a strong positive correlation was found between the first and second toe pressure measurements in patients with diabetes. The ability to utilize second toe pressures expands the opportunity to use toe pressures in the clinical setting and has the potential to alter clinical practice significantly with very little extra effort, expertise, and personnel requirements.

Objective: Toe systolic pressure is a component of the standard vascular and diabetic foot assessment. Until now, clinicians have measured only first toe pressure given a lack of evidence for measurements of the other toes. In diabetic patients, first toe measurements are often not possible because of ulceration or amputation. It was hypothesized that the adjacent second toe systolic pressure measurements would be interchangeable with those of the first toe.

Methods: A prospective study was performed on 100 participants with diabetes mellitus. Duplicate systolic toe pressures were measured in the first toe and adjacent second toe using the Systoe Automated Toe Pressure System, Systoe Photophlethysmograph Sensor Cuff, and occlusion cuffs measuring 120 × 25 mm for the first toe and 90 × 15 mm for the second toe. Correlation analysis was followed by Ordinary Least Products regression to detect and distinguish fixed and proportional bias between the two toe measurements. The acceptable limits of interchangeable results were defined as 5–10 mmHg.

Results: Correlation coefficient $r = 0.908$; $p < 0.001$. Eighty-two percent of the variations in the second toe measurements were accounted for by knowing the first toe measurements and vice versa. Ordinary Least Products regression showed no fixed or proportional bias between the two methods of measurement: second toe systolic pressure = (−0.579) + (1.038) * first toe systolic pressure. Repeatability analysis showed a 0.5% variation between duplicate measurements.

Conclusions: This is the first study which demonstrates that second toe systolic pressures are interchangeable with those of the first toe. Second toe pressures can be used in diabetic patients whose first toe pressures cannot be assessed.

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INTRODUCTION

The best technique to accurately measure lower limb and foot perfusion in diabetic patients has long been debated. Several methods have been proposed, including ankle-brachial pressure index, skin perfusion pressures, and transcutaneous oxygenation measurements to name a few. What is well recognized is that assessment of perfusion at the level of the ankle is often not a true reflection of distal foot perfusion, owing to the nature of peripheral micro-vascular dysfunction in diabetes.[1,2] Furthermore, ankle

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pressures are often falsely elevated in diabetic patients because of non-compressibility of calcified infra-popliteal vessels, known as Mönckeberg's sclerosis.[3–5] As such, toe-brachial pressure index (TBI) has been used in many institutions worldwide as the primary objective marker for distal foot perfusion.[6–8] In the *European Consensus Document on Critical Limb Ischaemia*, critical limb ischemia is defined on the basis of clinical findings (rest pain, ulcerations, and gangrene) and ankle pressure less than 50 mmHg or toe pressure less than 30 mmHg.[9] Toe pressures are commonly measured using photophlethysmography with an inflatable cuff around the hallux of the foot in question. Not uncommonly, patients with significant peripheral arterial occlusive disease (PAOD) have significant tissue loss, painful ulceration, isolated toe ischemia (in cases of distal embolization), or amputation of the first toe, making the measurement of first toe pressure not tolerable or possible. It was theorized that in such situations, the adjacent second toe could be used to obtain a toe pressure with good agreement to the first toe pressure as an objective marker of forefoot perfusion.

MATERIALS AND METHODS

Participants

From October to December 2013, 100 participants with a formal diagnosis of diabetes mellitus were recruited from diabetes out-patient clinics and in-patient wards at the authors' centre. Inclusion criteria included a diagnosis of diabetes mellitus, confirmed by review of medical records and recent pathology results (HbA1C $\geq$ 6.5% and fasting glucose $\geq$7 mmol/L), and having adjacent first and second toes present on one foot or both feet. Participants were excluded if they were under 18 years old, were unable to consent, had active ulceration on their first and/or second toes, had a vasomotor condition such as Raynaud's disease, were unable to lie still for the duration of the test, or had ingested caffeine or smoked within the previous hour. Patients were also excluded if the application and inflation of the pressure cuff proved to be prohibitively painful, or if the toe was too large to fit the maximum occlusion cuff size. Institutional ethics approval was granted by the Low Risk Ethics Committee at the regional hospital network.

Patients were informed about the study verbally and provided with written information by either the treating podiatrist or the vascular physician before consent was gained. Participants were asked to rest in a supine position for 15 minutes prior to measurements being taken. Restrictive clothing, such as shoes and tight socks, was removed and the temperature of the room was measured and maintained at a minimum of 22 °C to avoid error from vasoconstriction. Two measurements were taken on both the first and second toes of the eligible foot and recorded on an electronic spreadsheet.

Patient demographics are shown in Table 1. There was a preponderance of males (66) in the 100 patients studied with a mean age of 67.30 (15.25) years (range 29—90). Of the participants, 88 had a diagnosis of type 2 diabetes mellitus; 12 had type 1 diabetes mellitus. Most were being treated with insulin (47) or oral hypoglycemic agents (43); only 10 were being managed with dietary changes.

Table 1. Demographic details and diabetic status of the 100 participants.

Variable	Participants (n = 100)
Age, years	
Mean (SD)	67.30 (15.25)
Range	29—90
Gender	
Male	66
Female	34
Diagnosis	
Type 1 diabetes mellitus	12
Type 2 diabetes mellitus	88
Diabetes treatment	
Insulin	47
Oral hypoglycemic agents	43
Diet control	10

Instrument and procedure

Toe systolic pressure measurements were taken with the Systoe Automated Toe Pressure System (Atys Medical, Soucieu-en-Jarrest, France), which included the Systoe Photophlethysmograph (PPG) Sensor Cuff and two occlusion cuffs measuring 120 mm $\times$ 25 mm for the first toe and 90 mm $\times$ 15 mm for the second toe. This unit was chosen as it was familiar to the authors' staff; has an automated cuff inflator and the option to change the cuff size; can measure systolic toe pressures to less than 20 mmHg; and has been shown to have excellent interobserver and intra-observer reproducibility.[10]

Firstly, an occlusion cuff was placed around the base of the first toe (Fig. 1). Distal to this, the PPG sensor was secured to the pulp of the hallux with a double-sided transparent adhesive tape supplied by the manufacturer. The sensor was maintained in position with a second pneumatic cuff, which also acted as a blood draining cuff. If applied correctly, a pulse waveform would appear on the device screen. Activating the machine commenced an

Figure 1. Systoe automated toe pressure system (Atys medical, Soucieu-en-Jarrest, France).