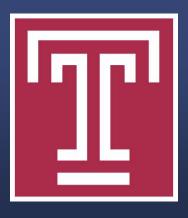
# Level of Agreement Between Diagnostic Peripheral Angiography and a Systematic Doppler Examination in the Setting of Lower Extremity Peripheral Arterial Disease.

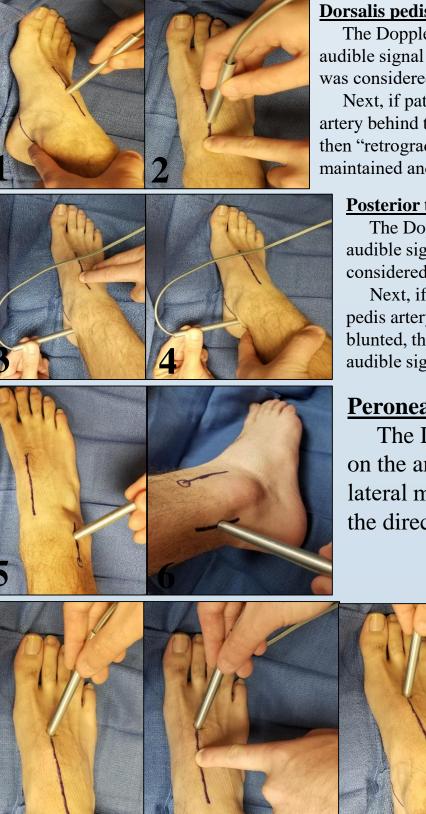


# **Statement of Purpose and Literature Review**

There are approximately 30 million diabetics in the US (equating to roughly 2000 patients with diabetes per doctor of podiatric medicine), and the diagnosis and treatment of diabetic foot disease forms a substantial portion of US healthcare expenditure dollars. One of the essential components of any diabetic foot evaluation is an assessmen of the arterial perfusion to the extremity. This is because the presence of peripheral arterial disease has been definitively established as a risk factor for wound formation, infection development, and both minor and major lower limb amputations [1-4]. This assessment might be initially performed by means of palpation of pedal pulses and the use of a handheld Doppler device, then through non-invasive vascular testing, and finally by means of peripheral angiography.

However, peripheral angiography is an invasive procedure that is not without potential complication. First, the direct costs of the surgical intervention should be considered [5]. Second, and perhaps most importantly, the use of a **Diagnostic angiography:** Following this systematic examination, the subject underwent angiography of the extremity as scheduled by the Vascular Surgery service. At a later date, a board-certified vascular contrast agent during the procedure frequently leads to renal impairment and injury, and other patients with endsurgeon (ETC) not involved in and without specific knowledge of either the angiogram or the systematic Doppler examination reviewed the distal run-off images and interpreted it as stage renal disease may not be candidates for the procedure [6]. And third, the interpretation of angiographic results follows: is a relatively subjective process potentially influenced by the level of clinical experience of the surgeon, patient -Proximal inflow (Iliac, Femoral and Popliteal arteries): "Normal vs. Abnormal" positioning and movement, the quality of the produced radiographic images, and the type of contrast agent utilized -Dorsalis pedis artery: "Normal patency vs. Abnormal patency vs. Absent" and "Antegrade vs. Retrograde". -Posterior tibial artery: "Normal patency vs. Abnormal patency vs. Absent" and "Antegrade vs. Retrograde". during the procedure [7]. -Anterior branch of the peroneal artery: "Patent" vs. Absent".

Given these potential concerns and limitations, the objective of this investigation was to determine the level of agreement between a systematic clinical Doppler examination of the foot and ankle and diagnostic peripheral angiography. Attinger et al have previously described a technique to determine the patency of the source arteries supplying the six angiosomes of the foot and ankle, as well as the direction of the flow utilizing sequential digital compression [8-10]. Our hypothesis was that performing a systematic Doppler assessment of the lower extremity angiosomal circulation might represent the basic interpretation of a distal run-off angiogram image performed by a vascular surgeon or interventionist. If a thorough physical clinical examination can provide the same information as the run-off image of a diagnostic angiogram, then it might decrease the need to perform this invasive surgical intervention simply as a diagnostic test.



## **Dorsalis pedis artery examination:**

The Doppler device was first placed on the dorsalis pedis artery on the dorsum of the foot between the ankle joint and tarsometatarsal joint. This was most commonly identified just medial to the extensor hallucis longus tendon. If an audible signal was heard, then the artery was considered "patent". If a triphasic or biphasic signal was heard, then the dorsalis pedis artery was considered "patent" and "normal". If a monophasic signal was heard, then the dorsalis pedis artery was considered "patent" and "abnormal". If no audible signal was heard, then the artery was considered "absent" and "abnormal". Next, if patent, an attempt was made to determine the direction of the flow through the dorsalis pedis artery. While the Doppler device was maintained on the dorsalis pedis artery, finger pressure was then used to compress the posterior tibial rtery behind the medial malleolus (Figure 1). If the Doppler signal was maintained and/or augmented, then flow through the dorsalis pedis artery was considered "antegrade". If the Doppler signal disappeared or was significantly blunted, then "retrograde" flow was suspected. In order to confirm "retrograde" flow through the dorsalis pedis artery, finger pressure was then used to compress the anterior tibial artery at the level of the ankle joint (Figure 2). If the audible signal was intained and/or augmented, then "retrograde" flow through the dorsalis pedis artery was considered confirmed.

## Posterior tibial artery examination

The Doppler device was then placed on the posterior tibial artery behind the medial malleolus. This was commonly found approximately halfway between the medial malleolus and most plantar and posterior aspect of the heel. If an audible signal was heard, then the artery was considered "patent". If a triphasic or biphasic signal was heard, then the posterior tibial artery was considered "patent" and "normal". If a monophasic signal was heard, then the artery was considered "patent" and "abnormal". If no audible signal was heard, then the artery was considered "absent" and "abnormal"

Next, if patent, an attempt was made to determine the direction of the flow through the posterior tibial artery. While the Doppler device was maintained on the posterior tibial artery, finger pressure was then used to compress the dorsalis pedis artery on the dorsum of the foot (Figure 3). If the Doppler signal was maintained and/or augmented, then flow through the posterior tibial artery was considered "antegrade". If the Doppler signal disappeared or was significantly blunted, then "retrograde" flow was suspected. In order to confirm "retrograde" flow through the posterior tibial artery, finger pressure was then used to compress the posterior tibial artery proximal to the Doppler device (Figure 4). If the audible signal was maintained and/or augmented, then "retrograde" flow through the posterior tibial artery was considered confirmed.

# **Peroneal artery examination:**

The Doppler device was then utilized to find the anterior and posterior terminal branches of the peroneal artery. The anterior branch of the peroneal artery was most commonly located on the anterior-lateral aspect of the ankle joint overlying the tibiofibular syndesmosis (Figure 5). The posterior branch of the peroneal artery was most commonly located posterior to the lateral malleolus (Figure 6). These arteries were assessed as "present" if an audible signal was heard versus "absent" if no audible signal was heard. No attempt was made to determine the direction or quality of the flow through the peroneal arteries.

# Vascular arch examination:

The Doppler device was then utilized to assess the vascular arch on the dorsal proximal first intermetatarsal space (Figure 7). If an audible signal was heard, then the vascular arch was considered "patent". If no audible signal was heard, then the vascular arch was considered "absent".

Next, if patent, an attempt was made to determine the direction of the flow through the vascular arch. While the Doppler device was maintained on the dorsal proximal first intermetatarsal space, finger pressure was then used to compress the dorsalis pedis artery on the dorsum of the foot (Figure 8). If the Doppler signal was maintained and/or augmented, then flow via the posterior tibial artery through the vascular arch was confirmed. If the Doppler signal disappeared or was significantly blunted, then "absent" flow via the posterior tibial artery through the vascular arch was considered. Then while the Doppler device was maintained on the dorsal proximal first intermetatarsal space, finger pressure was used to compress the posterior tibial artery behind the medial malleolus (Figure 9). If the Doppler signal was maintained and/or augmented, then flow via the dorsalis pedis artery through the vascular arch was confirmed. If the Doppler signal disappeared or was significantly blunted, then "absent" flow via the dorsalis pedis artery through the vascular arch was considered. Note that it was possible to observe a situation of dual antegrade flow through the vascular arch via both the dorsalis pedis artery and posterior tibial artery.

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Following approval by the Temple University Institutional Review Board, a systematic Doppler examination of the feet and ankles of subjects meeting study inclusion criteria was performed. Inclusion criteria consisted of subjects admitted to Temple University Hospital, with a history of lower extremity tissue loss (i.e. acute or chronic wound, soft tissue infection, bone infection, lower extremity gangrene, history of minor/major foot amputation), seen in consultation by the Foot and Ankle Surgery service during the admission, and who had a diagnostic lower extremity angiogram performed during the admission by the Vascular Surgery service. Exclusion criteria consisted of subjects less than age 18 or greater than age 90, those with a transmetatarsal amputation or other proximal partial foot amputation, and/or those with a history of lower extremity bypass of the index extremity. The goal of the systematic examination was primarily to determine the patency of the dorsalis pedis artery, posterior tibial artery, peroneal artery, and the vascular arch of the foot (i.e. the anastomosis between the dorsal and plantar arteries in the proximal first intermetatarsal space via the deep plantar perforating artery). Secondarily, an attempt to determine the direction of the flow (i.e. "antegrade" versus "retrograde") through the dorsalis pedis artery, posterior tibial artery, and vascular arch was performed by means of sequential digital occlusion. All examinations were performed by one of two study authors (TG and TH) under the supervision of a third study author (AJM). The specific technique is described in the

Methodology

accompanying figures below.

-Posterior branch of the peroneal artery: "Patent" vs. Absent".

-Vascular arch: "Patent" vs. Absent" and "Dorsally driven vs. Plantarly driven vs. dual "antegrade" flow vs. absent" Medial arterial calcific sclerosis

An evaluation was also performed to assess for the presence of lower extremity arterial calcification. This was defined as either an ankle-brachial index (ABI) >1.1, reporting of non-compressibility with non-invasive vascular testing, and/or radiographic evidence of vessel calcification in the proximal first intermetatarsal space (deep plantar perforating artery), anterior ankle (anterior tibial artery) and/or posterior ankle (posterior tibial artery).

Data points were considered categorical. A frequency count of agreement between the systematic Doppler examination and the diagnostic angiogram was performed. Data was stored in a password-protected and encrypted personal computer for subsequent analysis. All statistical analyses were performed by one author (AJM) using Microsoft Excel software (Microsoft, Remond, Washington).

> Dorsalis pedis quality (% ab Dorsalis pedia direction (% an Posterior tibia quality (% ab Posterior tibi direction (% ar Anterior bran the peroneal (% absent) Posterior braz the peroneal (% absent) Vascular arch (% absent)

1] [8] Muhs BE, Gagn Diab Rep 5(1): 24-9, 200 [2] Prompers L, Schape Tennvall G, Reike H, Sp focus on the differences [3] International Consen Diabetic Foot 2015. [4] Allen L, Powell-Co 2017 Jun;63(6):30-33, 20 [5] Hay JW, Lawler E, Y occlusive disease. Value 6] Schwartz RD, Rubin ] Louvel JP, Czernich carotid arteries and lower [8] Attinger CE, Evans K and revascularization. Pl [9] Clemens MW, Atting [10] Attinger CE1, Meyr

	Systematic Doppler examination	Diagnostic Angiography	Percent agreement
s artery	76.5%	88.2%	76.5%
s artery ntegrade)	52.9%	64.7%	70.6%
al artery	47.1%	52.9%	58.8%
al artery	82.4%	76.5%	76.5%
ch of artery	29.4%	52.9%	64.7%
nch of artery	29.4%	47.1%	70.6%
	29.4%	23.5%	82.4%

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Twenty extremities meeting criteria were investigated with three later excluded secondary to poor angiographic images precluding interpretation. Twelve (70.6%) of these seventeen were male with a mean  $\pm$  standard deviation (range) of 70.0  $\pm$  10.7 years (53-88). Seven extremities were "Black/African American", seven were "Other", and 3 were "White/Caucasian". Seven were "Hispanic/Latino" Eight of the extremities evaluated were right, seven were left and there was one bilateral case. Seven (41.2%) of the 17 extremities were found to have normal arterial inflow to the infrapopliteal trifurcation by the vascular surgeon, and 11(64.7%) of the 17 extremities were found to have evidence of medial arterial calcific sclerosis

## **Dorsalis pedis artery**

The Doppler examination found the dorsalis pedis artery to be "abnormal" or "absent" in 13 (76.5%) of 17 extremities. The direction of the flow was found to be "antegrade" in 9 (52.9%) extremities. "retrograde" in 3 (17.6%) extremities, and "absent" in 5 (29.4%) extremities. The angiogram was found to be "abnormal" in 15 (88.2%) of 17 extremities. The direction of the flow was found to be "antegrade" in 11 (64.7%) extremities, "retrograde" in 2 (11.8%) extremities, and "absent" in 4 (23.5%) extremities. There was agreement between the Doppler examination and the angiogram with respect to the quality of arterial flow in 13 (76.5%) of the 17 extremities, and agreement with respect to the direction of the arterial flow in 12 (70.6%) of the 17 extremities. In the 4 cases of disagreement with respect to the quality of the flow, the Doppler found "normal" whereas the angiogram found "abnormal" in three extremities, the proximal inflow was found to be "abnormal" in 3 extremities, and there was evidence of medial arterial calcific sclerosis in 2 extremities. In all 5 cases of disagreement with respect to the direction of the flow, the Doppler examination was found to have an "abnormal"

## **Posterior tibial artery**

The Doppler examination found the posterior tibial artery to be "abnormal" in 8 (47.1%) of 17 extremities. The direction of the flow was found to be "antegrade" in 14 (82.4%) extremities, "retrograde" in 1 (5.9%) extremity, and "absent" in 2 (11.8%) extremities. The angiogram was found to be "abnormal" in 9 (52.9%) of 17 extremities. The direction of the flow was found to be "antegrade" in 13 (76.5%) extremities, "retrograde" in 2 (11.8%) extremities, and "absent" in 2 (11.8%) extremities There was agreement between the Doppler examination and the angiogram with respect to the quality of arterial flow in 10 (58.8%) of the 17 extremities, and agreement with respect to the direction of the arterial flow in 13 (76.5%) of the 17 extremities.

In the 7 cases of disagreement with respect to the quality of the flow, the Doppler found "normal" whereas the angiogram found "abnormal" in four extremities, the proximal inflow was found to be "abnormal" in 3 extremities, and there was evidence of medial arterial calcific sclerosis in 4 extremities. In all 4 cases of disagreement with respect to the direction of the flow, the Doppler examination was found to have an "abnormal" signal.

## **Peroneal artery**

The Doppler examination found the anterior branch of the peroneal artery to be "absent" in 5 (29.4%) of 17 extremities and the posterior branch of the peroneal artery to be "absent" in 5 (29.4%) of 17 extremities. The angiogram found the anterior branch of the peroneal artery to be "absent" in 9 (52.9%) of 17 extremities and the posterior branch of the peroneal artery to be "absent" in 8 (47.1%) of 17 extremities. There was agreement between the Doppler examination and the angiogram with respect to the anterior branch of the peroneal artery in 11 (64.7%) of 17 extremities. The Doppler examination found the artery to be "patent" in 5 (83.3%) of the 6 cases of disagreement. There was agreement between the Doppler examination and the angiogram with respect to the posterior branch of the peroneal artery in 12 (70.6%) of 17 extremities. The Doppler examination found the artery to be "patent" in 4 (80.0%) of the 5 cases of disagreement.

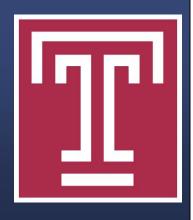
## Vascular arch

The Doppler examination found the vascular arch to be "patent" in 12 (70.6%) of 17 extremities. The direction of the flow through the arch was found to be "dorsally driven" in 3 (17.6%) extremities, "plantarly driven" in 7 (41.2%) extremities, "dual antegrade flow" in 2 (11.8%) extremities, and "absent" in 5 (29.4%) extremities. The angiogram found the vascular arch to be "present" in 13 (76.5%) of 17 extremities. The direction of flow through the arch was found to be "dorsally driven" in 5 (29.4%) extremities, "plantarly driven" in 5 (29.4%) extremities, "dual antegrade flow" in 3 (17.6%) extremities, and "absent" in 4 (23.5%) extremities. There was agreement between the Doppler examination and the angiogram with respect to the presence of the vascular arch in 14 (82.4%) of 17 extremities, and agreement with respect to the direction of flow through the vascular arch in 14 (82.4%) of 17 extremities. In the 3 cases of disagreement with respect to the patency of the arch, it was visualized on the angiogram, but inaudible on the Doppler.

As with any scientific investigation, critical readers are encouraged to review the study design and specific results in order to reach their own conclusions, while the following represents our conclusions based on the specific results. As scientists, we also never consider data to be definitive, but do think that these results are worthy of some attention and future investigation.

-We primarily observed relatively high levels of agreement between a systematic Doppler examination of the foot and ankle and diagnostic angiography. Levels of agreement with respect to artery patency and quality ranged from 58.8% to 82.4%, and levels of agreement with respect to arterial flow direction ranged from 70.6% to 76.5%. We interpret these results to mean that a comprehensive physical examination of the arterial flow to the foot and ankle with a Doppler device might possibly serve as a reasonable surrogate to diagnostic angiography in some cases of diabetic foot disease. -Subjectively, we noted that the angiogram might have been more sensitive with respect to assessing the patency and quality of the dorsalis pedis artery, while the Doppler examination might have been more sensitive with respect to the patency of the peroneal arteries. The most disagreement we observed was with respect to the patency and quality of the posterior tibial artery. And although it is likely the sample size is not robust enough to draw definitive conclusions, we did not observe any trends indicating that proximal inflow disease and/or arterial calcification had a substantial effect on the level of agreement. -We embrace the fact that all investigations have limitations, and this had several important ones to consider. First, we investigated a limited amount of subjects from a single institution, and therefore these results might not be representative of a broader population sampling. Second, all subjects had some degree of peripheral arterial disease, and therefore we cannot be sure of the influence of this on the pre-test probability of results. Third, the categorical nature of the data established by the study design meant that there was a 50% likelihood of agreement simply by chance, and therefore a more advanced statistic than frequency of agreement, such as the kappa statistic, might have been considered.

In conclusion, the results of this investigation provide evidence that a comprehensive physical examination of the arterial flow to the foot and ankle with a Doppler device might serve as a reasonable surrogate to diagnostic angiography in some cases of diabetic foot disease. We hope that the results of this investigation increase the body of knowledge with respect to the arterial assessment of the diabetic foot.



# Results

# Discussion