A prospective evaluation of transcutaneous oxygen measurements in the management of diabetic foot problems

Jeffrey L. Ballard, MD, Clifford C. Eke, MD, T. J. Bunt, MD, and J. David Killeen, MD, *Loma Linda, Calif.*

Purpose: To test the hypothesis that lower extremity transcutaneous oxygen ($TcPO_2$) measurements can accurately predict severity of foot ischemia and can be used to select appropriate treatment (conservative versus operative) for patients with diabetes and tissue necrosis or ischemic rest pain.

Methods: Fifty-five patients with 66 limbs were prospectively treated from June 1993 to July 1994. Noninvasive hemodynamic arterial assessment and $TcPO_2$ mapping of the involved limb were obtained before treatment was selected. If the transmetatarsal $TcPO_2$ level was 30 mm Hg or greater, the patient's foot problem was managed conservatively with local wound care, debridement, or a minor foot amputation. If the transmetatarsal $TcPO_2$ level was less than 30 mm Hg, arteriography was performed with the anticipated need for vascular reconstruction. The endpoints for determining treatment success or failure were complete wound healing or relief of ischemic rest pain.

Results: Thirty-one of 36 (86%) limbs with an initial transmetatarsal $TcPO_2$ level of 30 mm Hg or greater were treated successfully with conservative care, including 73% (11 of 15 feet) of limbs without a palpable pedal pulse. After either bypass or angioplasty, 20 of 24 (83%) limbs achieved a transmetatarsal $TcPO_2$ level greater than 30 mm Hg and had complete resolution of their presenting foot problem. An initial or postintervention transmetatarsal $TcPO_2$ level of 30 mm Hg or greater was more accurate (90%, $p = 0.001$) than a palpable pedal pulse (65%, $p = 0.009$), in predicting ultimate wound healing or resolution of rest pain.

Conclusions: $TcPO_2$ mapping is a useful noninvasive modality that can prospectively determine severity of foot ischemia, aid in selecting appropriate treatment for patients with diabetes and foot salvage problems, and decrease the total cost of such care. (J VASC SURG 1995;22:485-92.)

Successful treatment of the patient with diabetes and limb-threatening ischemia requires an accurate assessment of limb perfusion. A patient's symptoms may be misleading. Physical examination of peripheral pulses or the ankle/brachial index (ABI) may be inaccurate. Often, the cause of the presenting foot problem is likely to be multifactorial. A noninvasive, inexpensive, and reproducible diagnostic test that could reliably predict severity of foot ischemia would be useful. Commonly used noninvasive lower extremity hemodynamic studies lack discriminative accuracy.[1-4] Arteriography is invasive, expensive, and carries a small but well-defined set of associated complications.[5-6] However, transcutaneous measurement of the partial pressure of oxygen ($TcPO_2$) has application in peripheral vascular surgery. It has been used for monitoring results of arterial revascularization, assessing limb ischemia, and determining an optimal amputation level.[1-4,7-12]

This study tests the hypothesis that $TcPO_2$ measurements can be used to select appropriate treatment (conservative versus operative) for patients with diabetes with severe chronic foot ischemia and its complications.

PATIENTS AND METHODS

During the period June 1993 to July 1994, all patients with diabetes and ischemic rest pain or pedal

From the Division of Vascular Surgery, Loma Linda University Medical Center, Loma Linda.

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Reprint requests: Jeffrey L. Ballard, MD, Loma Linda University Medical Center Division of Vascular Surgery, Room 2586A, 11234 Anderson St., Loma Linda, CA 92354.

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tissue necrosis were prospectively entered into the study.[13] A detailed medical history and physical examination was obtained by use of conventional and time-tested techniques as follows: pedal pulses were documented by the attending surgeon as either palpable or nonpalpable; a bilateral lower extremity noninvasive arterial evaluation recorded Doppler waveforms, segmental limb pressures, and calculated ABIs. In addition, transcutaneous oxygen mapping of the involved limb was performed (Novametrix System 800 monitor; Novametrix Medical Systems, Wallingford, Conn.) before treatment was selected.

$TcPO_2$ mapping was performed at ambient room temperature with the patient in the supine position. Oxygen inhalation, change in limb position, and chest wall normalized $TcPO_2$ values were not used in this study.[11,14,15] The Novametrix 800 monitor has three modified Clark electrodes that simultaneously record skin oxygen tension. Measurements were recorded from the dorsum of the foot (transmetatarsal), the medial side of the calf 8 to 10 cm below the knee (BK), and the medial side of the thigh 8 to 10 cm above the knee (AK). On the skin surface, the oxygen sensor was held in place by a double-sided adhesive ring, and the controlled heating element around the sensor was adjusted to 44° C. Heating the sensor created local skin hyperemia, a decrease in flow resistance, and compensatory arterialization of capillary blood. This effectively raises the Po_2 and decreases the Pco_2, values toward arterial levels.[16,17] Stable $TcPO_2$ readings were usually achieved in 20 to 30 minutes.

Based on clinical experience and amputation level determination data, an absolute transmetatarsal $TcPO_2$ measurement of 30 mm Hg was used as the critical value to select a treatment option.[7-9] If the level was 30 mm Hg or greater, the patient's foot was managed conservatively with local wound care, wound debridement, or a minor foot amputation. If the level was less than 30 mm Hg, arteriography of the involved limb was performed to plan arterial reconstruction to improve foot perfusion.

There were 34 (62%) men and 21 (38%) women with diabetes with a mean age of 67 years (range 34 to 87) entered into this study. They were admitted with 66 threatened feet for evaluation. Treatment indications included nonhealing ulcer (35 feet, 53%), gangrene (25 feet, 38%), and rest pain (6 feet, 9%). Thirty-three (60%) patients had insulin-dependent diabetes, and the others (22 patients, 40%) had noninsulin-dependent diabetes. Risk factors for peripheral vascular disease, in addition to diabetes mellitus, included coronary artery disease (34 patients, 62%), hypertension (39 patients, 71%), hypercholesterolemia (31 patients, 56%), and history of smoking (15 patients, 27%). Additionally, 12 (22%) patients were undergoing dialysis, and seven (13%) patients had a history of a previous stroke. In this medically compromised group, 31% (17 patients), had a previous history of lower extremity amputation (toe, six patients; transmetatarsal, three patients; below-knee (BK), five patients; above-knee (AK), three patients).

All patients were examined at weekly or biweekly intervals. Follow-up $TcPO_2$ mapping, repeat pedal pulse examination, and recalculation of the ABI was performed in all patients who had a procedure designed to improve foot perfusion. Dressing changes were either performed by a family member or a home health care nurse specialist. The endpoints for determining treatment success or failure were complete wound healing or relief of ischemic rest pain. All limbs, except four, reached these endpoints. Follow-up ranged from 2 to 15 months (mean 8 months). No patient was lost to follow-up.

Statistical analysis. Accuracy statistics were derived by use of 2×2 tables, and other conditional variables were evaluated by use of chi-squared or Fisher's exact test. The Student t statistic was used for testing the significance of differences in the means of independent and paired samples. A significant difference for any statistical analysis was assumed when $p < 0.05$. Initial and follow-up ABIs unable to be calculated because of noncompressible vessels were not used for statistical analysis.

RESULTS

In the conservative treatment group (38 feet, 57.6%) with initial transmetatarsal $TcPO_2$ greater than 30 mm Hg, the mean ABI was 0.91 in the involved limb and the mean initial $TcPO_2$ levels were as follows: AK, 59 mm Hg; BK, 54 mm Hg; transmetatarsal, 50 mm Hg. A pedal pulse was palpated in 21 feet, whereas 17 feet did not have a palpable pedal pulse. Conservative treatment consisted of local wound care (16 feet, 42%), local wound debridement (18 feet, 47%), or a minor foot amputation (4 feet, 11%) (Table I). Thirty-six of 38 feet were monitored to the selected endpoints. Two patients (two limbs with palpable pedal pulses) excluded from outcome analysis died 2 and 4 months after initiation of conservative care but before complete resolution of their presenting foot problem.

Thirty-one of 36 (86%) limbs in this group were treated successfully, including 73% (11/15 feet) of limbs without a palpable pedal pulse. The mean time

to wound healing was 6.85 weeks. There were five treatment failures. One patient had a successful transmetatarsal amputation after conservative efforts failed to heal multiple nonhealing toe ulcers. The other four patients underwent arterial reconstruction (two femoropopliteal, one femorotibial, one popliteal-popliteal), with three successes and one failure, necessitating a BK amputation.

In the operative treatment group (28 feet, 42.4%) with initial transmetatarsal $TcPO_2$ less than 30 mm Hg, the mean ABI in the involved limb was 0.57, and $TcPO_2$ mapping demonstrated the following mean values: AK, 55 mm Hg; BK, 41 mm Hg; transmetatarsal, 11 mm Hg. No patient in this group had a palpable pedal pulse, and all patients with rest pain had low transmetatarsal $TcPO_2$ measurements. Interventions based on arteriography included arterial reconstruction (16 limbs, 57%), angioplasty (eight limbs, 29%), primary major amputation (two limbs, 7%), and pedal vessel exploration (one limb, 3.5%). One other limb (3.5%) demonstrated only a proximal occlusion of the lateral branch of the plantar artery without another significant arteriographic abnormality (Table I). Twenty-six of 28 feet were monitored to the selected endpoints. There were no deaths, but two patients without a distal target vessel suitable for bypass underwent primary major lower extremity amputation and were excluded from outcome analysis.

After either bypass or angioplasty, 20 of 24 (83.3%) limbs achieved a transmetatarsal $TcPO_2$ level greater than 30 mm Hg. The $TcPO_2$ improvement was most marked at the transmetatarsal level where the mean value increased from 11 to 42 mm Hg ($p = 0$). At the BK and AK positions, the mean $TcPO_2$ level improved from 40 to 49 mm Hg ($p = 0.11$) and from 56 to 60 mm Hg ($p = 0.43$), respectively. Twenty-two of 26 (85%, $p = 0.0003$) limbs in this group had complete resolution of their presenting foot problem. This includes one limb with a persistent transmetatarsal $TcPO_2$ level less than 30 mm Hg despite successful peroneal artery bypass, and one limb that had an unnecessary angiogram as the follow-up transmetatarsal $TcPO_2$ level after edema/cellulitis resolution was greater than 30 mm Hg. The mean time to wound healing was 9.52 weeks. Treatment failures eventually led to three BK amputations (one failed necessitating revision to the AK level) and 1 AK amputation.

Overall, the pedal pulse examination was more accurate than the ABI in predicting $TcPO_2$ values above or below 30 mm Hg at the foot level (74%, $p = 0.000006$ vs 68%, $p = 0.011$). An abnormal arteriogram was predicted by both a low transmetatarsal $TcPO_2$ level and the absence of a palpable pedal pulse (27 of 28 threatened limbs, 96%), but not an ABI less than 0.60 (52%). The presence of a pedal pulse was 100% accurate for identifying limbs with a transmetatarsal $TcPO_2$ greater than 30 mm Hg (21 of 21 feet), but there were 17 additional limbs with a measurement greater than 30 mm Hg and no palpable pedal pulse. After arterial reconstruction or angioplasty, a transmetatarsal $TcPO_2$ level of 30 mm Hg or greater was highly accurate (96%, $p = 0.0003$) in predicting a successful outcome. Ultimately, an initial or postintervention transmetatarsal $TcPO_2$ level of 30 mm Hg or greater was more accurate (90%, $p = 0.001$) than a palpable pulse (65%, $p = 0.009$) in predicting ultimate wound healing or resolution of rest pain. An ABI greater than 0.60 was also associated with a successful outcome (89%, $p = 0.06$), but because of noncompressible vessels, the ABI was only able to be calculated in 41/62 (66%) limbs (Table II).

The total cost for $TcPO_2$ mapping of a lower extremity is $93.88. This figure includes direct and indirect facility costs ($56.70) for the 30-minute study with no variation in cost for a unilateral or bilateral study except for the increased time (an extra 30 minutes) involved for the vascular technician, plus the current physician reimbursement based on the Medicare-RVU scale ($37.18). The total cost for a diagnostic lower extremity arteriogram, including nursing staff, supplies, usual room time of 2 hours,

Table I. Interventions based on initial transmetatarsal $TcPO_2$ level

Transmetatarsal $TcPO_2 \geq 30$ mm Hg (38 feet, 57.6%)	
Wound debridement	18 feet (47%)
Local wound care	16 feet (42%)
Minor foot amputation	4 feet (11%)
Transmetatarsal $TcPO_2 < 30$ mm Hg (28 feet, 42.4%)	
Revascularization	16 limbs (57%)
Fem-Fem 1	
Fem-Pop 4	
Fem-Tib 5	
Fem-Pedal 1	
Pop-Tib 3	
Pop-Pedal 2	
Angioplasty	8 limbs (29%)
Iliac 1	
SFA 4	
Tibial 3	
Primary major amputation	2 limbs (7%)
BK 2	
Pedal vessel exploration	1 foot (3.5%)
Essentially normal arteriogram	1 limb (3.5%)

Fem, Femoral; *Pop,* popliteal; *Tib,* tibial; *SFA,* superficial femoral artery.

Table II. Accuracy statistics for predicting resolution of diabetic foot salvage problems

	Sensitivity (%)	*Specificity (%)*	*Predictive value*		*Accuracy (%)*
			Positive (%)	*Negative (%)*	
Initial or postintervention transmetatarsal $TcPO_2 \geq 30$ mm Hg (62/62 limbs):	98	44	91	80	90
Palpable pedal pulse (62/62 limbs):	60	89	97	28	65
ABI ≥ 0.60 (41/62 limbs):	94	40	92	50	88

Table III. Algorithm for elective management of the patient with diabetes and limb-threatening foot ischemia

If TM $TcPO_2 \geq 30$ mm Hg (with or without a palpable pedal pulse
  Outpatient wound care, wound debridement, or minor foot amputation
If TM $TcPO_2 < 30$ mm Hg or conservative treatment is unsuccessful after 4 to 6 weeks
  Arteriography, with revascularization as needed
If TM $TcPO_2 < 30$ mm Hg and there is pedal edema or cellulitis
  Repeat test after resolution, before proceeding with arteriography
For calcaneal gangrene/nonhealing ulcer
  Use higher TM $TcPO_2$ threshold of 40 mm Hg or selective $TcPO_2$ mapping of the forefoot and hindfoot
  Arteriography after 2 to 4 weeks of unsuccessful conservative treatment.

TM, Transmetatarsal.

and the procedure code, is $1052.73 ($485.45 for staff, supplies, and angiography suite, plus $107.93 for outpatient charges, plus $459.35 for the allowable professional component based on the Medicare-Relative Value Unit scale).

DISCUSSION

This study is unique in that $TcPO_2$ mapping was used prospectively to determine treatment for patients with diabetes and limb-threatening ischemia. ABIs and pedal pulses were carefully recorded, but clinical decisions were based on an absolute transmetatarsal $TcPO_2$ level of 30 mm Hg with the patient in the supine position and breathing room air.[9] A transmetatarsal $TcPO_2$ level greater than 30 mm Hg at the onset of conservative treatment or after arterial reconstruction/angioplasty was highly accurate (90%, $p = 0.001$) in predicting ultimate resolution of pedal gangrene, nonhealing ulceration, or ischemic rest pain.

As expected, in this group of patients with diabetes, an ABI could not be calculated in all limbs. Even with compressible vessels, ABIs were not reliable in predicting either abnormal arteriograms or $TcPO_2$ levels (> 30 mm Hg) adequate to support major wound healing. However, the absence of a pedal pulse was highly predictive of an abnormal arteriography result, and a palpable pedal pulse was 100% (21 of 21 limbs) correct in identifying feet with a transmetatarsal $TcPO_2$ greater than 30 mm Hg, 20 of which were successfully treated. Nevertheless, 11 of 15 limbs without a palpable pulse but with a transmetatarsal $TcPO_2$ greater than 30 mm Hg also healed with conservative care only. Thus neither ABIs nor pedal pulses were sufficiently discriminating to be used to make a clinical decision with regard to ultimate wound healing or resolution of rest pain.

If absence of pedal pulses had been the indication for arteriography, 45 limbs would have been subjected to this examination. In fact, only 31 limbs needed arteriography (27/28 limbs with an initial transmetatarsal $TcPO_2$ level less than 30 mm Hg, and 4/5 treatment failures with an initial transmetatarsal $TcPO_2$ level of 30 mm Hg or greater). The nonessential 14 arteriograms would have cost $14,738.22. In contrast, the 14 $TcPO_2$ studies cost $1314.32.

Certainly patients with diabetes and without pedal pulses do have arteriosclerotic lesions, some of which can be reconstructed. This study demonstrates that such surgical revascularization is not obligatory. In fact, well-performed $TcPO_2$ measurements can predict distal ischemic wound healing in 90% of cases. Furthermore, conservative management is not only cost-effective when compared with surgical or angioplasty revascularization, but time to lesion healing is not statistically significantly different between the two groups (6.84 weeks vs 9.52 weeks, $p = 0.169$).

A critical analysis of treatment failures and incorrect treatment selection demonstrates the fallibility of $TcPO_2$ measurements in certain clinical situations and the complex nature of diabetic foot

problems. In the conservative treatment group, four of five treatment selection failures had a transmetatarsal $TcPO_2$ value less than 34 mm Hg and had calcaneal gangrene or nonhealing ulceration. The foot of the fifth patient failed to improve with not only conservative care, but also with arterial reconstruction, and the patient underwent a BK amputation despite an initial transmetatarsal $TcPO_2$ level of 42 mm Hg. In the group of patients with an initial transmetatarsal $TcPO_2$ less than 30 mm Hg, one patient's transmetatarsal $TcPO_2$ level improved from 1 to 19 after superficial femoral artery angioplasty, but the ulcerated foot lesion did not heal. She then had femorotibial bypass and a free-flap to cover the dorsum of her foot. The transmetatarsal $TcPO_2$ level improved to 30 mm Hg. This combined procedure was ultimately successful. One patient had pedal vessel exploration, but no suitable distal target vessel was found. He then failed a minor foot amputation. Two patients had a major amputation for ascending pedal sepsis despite a patent bypass graft. One other patient with pedal edema, cellulitis, and a transmetatarsal $TcPO_2$ measurement of 25 mm Hg had an unnecessary arteriogram, because the foot problem resolved with conservative care. Follow-up $TcPO_2$ mapping demonstrated the transmetatarsal value to be greater than 30 mm Hg after resolution of pedal cellulitis and edema.

An absolute transmetatarsal $TcPO_2$ level of 30 mm Hg or greater appears to be an accurate cutoff point for the selection of conservative or operative treatment for almost all diabetic foot problems. The conservative management scheme, however, requires diligent patient follow-up. There must be a commitment by the surgeon to perform office debridements and staged procedures (i.e., minor foot amputations or split-thickness skin grafts). Proper outpatient wound care is essential. A higher transmetatarsal $TcPO_2$ threshold (40 mm Hg) may be required to manage successfully calcaneal gangrene or some very severe nonhealing ulcerations.

An arteriographic abnormality that requires angioplasty or arterial reconstruction can be expected in most instances when the transmetatarsal $TcPO_2$ level is less than 30 mm Hg. However, cellulitis and significant foot edema may confound the accuracy of $TcPO_2$ mapping. In this circumstance, if the transmetatarsal $TcPO_2$ level is found to be less than 30 mm Hg, the test should be repeated after hospitalization, bed rest, leg elevation, intravenous antibiotics, and resolution of the edema.

$TcPO_2$ mapping is accurate, noninvasive, and relatively inexpensive. The study can be used prospectively to select appropriate treatment (Table III) for patients with diabetes and limb-threatening ischemia and may obviate the need for arteriography to determine severity of foot ischemia, even in patients with diabetes without pedal pulses and low ABIs.

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REFERENCES

1. Hauser CJ, Klein SR, Mehringer CM, Appel P, Shoemaker WC. Superiority of transcutaneous oximetry in noninvasive vascular diagnosis in patients with diabetes. Arch Surg 1984;119:690-4.
2. Hauser CJ, Klein SR, Mehringer CM, et al. Assessment of perfusion in the diabetic foot by regional transcutaneous oximetry. Diabetes 1984;33:527-31.
3. Modesti PA, Boddi M, Poggesi L, et al. Transcutaneous oximetry in evaluation of the initial peripheral artery disease in diabetics. Angiology 1987;38:457-61.
4. Hauser CJ. Tissue salvage by mapping of skin surface transcutaneous oxygen tension index. Arch Surg 1987;122: 1128-30.
5. Kim D, Orron DE. Techniques and complications of angiography. In: Kim D, Orron DE, eds. Peripheral vascular imaging and imervention. St. Louis: Mosby–Year Book, 1992:83-109.
6. Weisberg LS, Kurnik PB, Kumik BRC. Risk of radiocontrast neuropathy in patients with and without diabetes mellims. Kidney Int 1994;45:259-65.
7. Fronek A. Clinical experience with transcutaneous Po_2 and Pco_2 measurements. In: Bernstein EF, ed. Vascular Diagnosis. St. Louts: Mosby–Year Book, 1993:620-5.
8. Malone JM, Ballard JL. Amputation level determination techniques. In: Bernstein EF, ed. Vascular diagnosis. St. Louis: Mosby–Year Book, 1993:568-74.
9. Quigley FG, Faris IB. Transcutaneous oxygen tension measurements in the assessment of limb ischemia. Clin Physiol 1991;11:315-20.
10. Lalka SG, Malone JM, Anderson GG, Hagaman RM, McIntyre KE, Bernhard VM. Transcutaneous oxygen and carbon dioxide pressure monitoring to determine severity of limb ischemia and to predict surgical outcome. J VASC SURG 1988;7:507-14.
11. Moosa HH, Peitzman AB, Makaroun MS, Webster MW, Steed DL. Transcutaneous oxygen measurements in lower extremity ischemia: effects of position, oxygen inhalation, and arterial reconstruction. Surgery 1988;103:193-8.
12. Ballard JL, Malone JM. Amputation in the diabetic. In: Rutherford RB, ed. Seminars in vascular surgery. Philadelphia: WB Saunders, 1992:257-63.
13. Rutherford RB, Flanigan DP, Gupta SK, et al. Suggested standards for reports dealing with lower extremity ischemia. J VASC SURG 1986;4:80-94.
14. Hauser CJ, Appel P, Shoemaker WC. Pathophysiologic classification of peripheral vascular disease by positional changes in regional transcutaneous oxygen tension. Surgery 1984;95:689-93.
15. Larsen JF, Jensen BV, Christensen KS, Egeblad K. Forefoot

transcutaneous oxygen tension at different leg positions in patients with peripheral vascular disease. Eur J Vasc Surg 1990;4:185-9.
16. Baumbach P. Understanding transcutaneous Po_2 and Pco_2 measurements. Copenhagen: Radiometer A/S, 1986:1-54.
17. Steenfos HH, Baumbach P. Transcutaneous Po_2 in peripheral vascular disease. Radiometer A/S, Copenhagen 1986:1-18.

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DISCUSSION

Dr. James M. Malone (Phoenix, Ariz.). This prospective randomized study evaluated 66 feet at risk in 55 patients with diabetes. All patients were admitted with ischemic rest pain or tissue necrosis. Sixty percent of the patients had insulin-dependent diabetes, and 22% were undergoing long-term hemodialysis. Patients were randomized into two study groups, conservative wound management with/without minor foot amputation or angiography with vascular reconstruction and/or angioplasty, on the basis of transcutaneous oxygen measurements in the affected foot. A transcutaneous measurement of greater than 30 mm Hg led to conservative treatment, whereas a measurement of less than 30 mm Hg led to invasive diagnostic therapy. The study endpoints were resolution of the presenting foot problem or death. The study duration was 1 year.

This study concluded that 86% of patients with a transcutaneous oxygen measurement greater than 30 mm Hg healed with conservative therapy, whereas 83% of patients with a transcutaneous oxygen measurement less than 30 mm Hg healed after angioplasty or vascular reconstruction. In addition, the authors concluded that transcutaneous oxygen measurements were more accurate than pedal pulses or ABIs. The latter conclusion is to be expected given the noncompressible nature of the tibial arteries in patients with diabetic peripheral vascular disease.

There were five patient/limb failures in the conservative therapy group. Four of the five failures were in patients with transcutaneous oxygen measurements greater than 30 mm Hg but less than 34 mm Hg. In addition, these failures were all associated with calcaneal gangrene. There were four limb failures in the invasive therapy group and all failures occurred for the usual reasons.

Why not raise your conservative threshold measurement to 35 mm Hg? That level would have given you a success rate of 35 of 36 patients. On the other hand, four of five failures occurred in patients with calcaneal gangrene. It is my guess that those patients form a special subgroup of diabetic foot problems. Should those patients be a special subgroup rather than included with other more typical diabetic foot problems?

What did the arteriograms look like in the patients with calcaneal gangrene both before and after reconstruction? Most of us have had patients with successful distal tibial bypass procedures, but a "black hole" of nonperfusion over the area of calcaneal gangrene. Again, should these patients be stratified into a subgroup?

This is a short-term study. What long-term follow-up is available? Do you plan to continue to monitor these patients? In addition, because the expected contralateral limb loss rate in this group of patients is 7% to 12% per year, what happened to the opposite limb/nonaffected extremity/foot?

I encourage you to repeat this study as a multicenter, prospective randomized trial with stratification to help analyze insulin use, subgroup classification of diabetic foot problems, the role of patient education, foot and shoe/orthotic care, and the quality of patient follow-up.

Dr. Jeffrey L. Ballard. Patients with calcaneal gangrene form a special subgroup. The $TcPO_2$ threshold may need to be 35 or 40 mm Hg. As a result of this study, we pursue arteriography early if the $TcPO_2$ levels are marginal. These patients need aggressive treatment. It is not uncommon for the patient to need either a free vascularized tissue transfer or a local myocutaneous tissue rotation after revascularization. Even though arteriograms do occasionally show a "black hole," free flaps based on a distal bypass graft can be used to cover severely ischemic open wounds.

Regarding the contralateral limb, two or three patients have had problems, and they are treated according to this algorithm. So far we have not seen limb loss in the contralateral limb, but our follow-up is short.

With regard to long-term follow-up, we have a stable patient population. Long-term data on the management of these diabetic foot problems will be available in the next few years.

Dr. Robert B. Rutherford (Denver, Colo.). I believe it's very difficult to apply a single absolute cutoff point, such as 30 mm Hg. I realize there's some basis for this in the literature, as Dr. Malone has pointed out, but we found that, below 20 mm Hg, nothing is going to heal, and, above 40 mm Hg, almost everything will heal; but there's an in-between zone where it is not possible to predict healing with accuracy, and that's where a lot of these cases fall.

So we've taken a different approach on the basis of the cost-effectiveness of starting with the cheapest test first. Darrell Jones worked out an algorithm for us to use. Basically, if we can get a pulsatile plethysmographic tracing near the level of the lesion, that tells us that healing will occur.

If the plethysmographic tracing is "flat line," then you take a toe pressure. The toe pressure has a similar range to the tissue oxygen level. Healing will not occur below 20 mm Hg, but it will above 40 mm Hg. So that eliminates more at each end. Usually with those two inexpensive tests that are readily performed in your vascular laboratory, you are able to make the decision in more than 80% of the cases. If the results of these two simple tests don't decide it, we then go to tissue oxygen determinations, which take close to an hour to perform, with membrane warming and equilibration.

For the calcaneal ulcers and unusual lesions like that, which I agree are a special subgroup, that are hard to predict, we use thallium perfusion scanning. If you have a hyperemic zone around the lesion, with a more than 2:1 ratio of hyperemia to background, then those can be expected to heal with conservative measures.

So what I am suggesting is, rather than respond rigidly to values on either side of the single-tissue oxygen end point, you could use cheaper and more readily available tests in most of the cases and get the same or better results and probably end up without the 14% failure rate you report.

Dr. Ballard. We don't use the other noninvasive methods that you described. We specifically did not want to repeat a study of multiple different diagnostic modalities. Our goal was to choose one study ($TcPO_2$), use it prospectively, and validate its ability to screen patients with diabetes for foot ischemia.

Dr. Kaj H. Johansen (Seattle, Wash.). Dr. Rutherford makes the point that a patient with diabetes needs to have a toe to perform digital plethysmography, and I agree. We have unpublished data that show a very high correlation between digital pressures and $TcPO_2$s. There may be a real virtue in a study (digital plethysmography) that can be performed in 1 or 2 minutes rather than 30 minutes ($TcPO_2$).

That notwithstanding, this is a prospective randomized trial of an important modality in a patient population that we're going to be seeing more and more of.

Dr. Calvin B. Ernst (Detroit, Mich.). We learned from Dr. Malone's discussion that 22% of the patients were undergoing dialysis. This is a subgroup of patients in whom we have had disappointing results after limb salvage procedures. They have dismal results after revascularization and frequently require amputations. Please expand on this subgroup.

Dr. Ballard. We have looked at patients with diabetes undergoing popliteal-tibial bypass and patients with diabetes and these foot problems and have not seen a decidedly dismal result in those patients who were undergoing hemodialysis. We do not change our treatment algorithm for patients undergoing dialysis.

Dr. William J. Quiñones-Baldrich (Los Angeles, Calif.). Excluding patients who have calcaneal problems or gangrene where you can have a palpable dorsalis pedal pulse and still have a heel that is very ischemic, the group of patients who had palpable pulses were the ones that you were able to discriminate with $TcPO_2$ measurement. Those who did not have palpable pulses required an arteriogram and eventual revascularization. It seems to me the message here is that if the patient has a palpable pulse and no problem in the heel, that you probably can treat that patient conservatively and even skip the $TcPO_2$ reserving the test for those patients who don't have a palpable pulse, helping to stratify those into conservative or more aggressive measures. Could you comment on that?

Dr. Ballard. You are probably correct. A patient with diabetes with a palpable foot pulse will very likely have their foot problem heal with conservative treatment. In this prospective study every patient had $TcPO_2$ mapping. There will be an occasional patient in whom conservative treatment will fail with an adequate $TcPO_2$ level and a palpable foot pulse.

Dr. J. Dennis Baker (Los Angeles, Calif.). I am concerned about your cost estimates. It appears that you are presuming that conservative management is based on outpatient therapy.

At the Veterans Affairs Hospital, conservative therapy often ends up as hospitalization. So if you have a moderate to long hospitalization before you accept the fact that your conservative management has failed, you tack that onto the cost of the vascular reconstruction and angiography. Was this factor considered in the cost estimates?

Dr. Ballard. Conservative treatment was generally in an outpatient setting. We have very aggressive home health care nursing, which has been the key. Outpatient care has to be diligently monitored by the surgeon to be successful.

Dr. Wesley S. Moore (Los Angeles, Calif.). This question is directed toward the failures in which you had calcaneal ulceration. If you've got a situation in which there's disconnection between the anterior and posterior circulation of the foot and if the ulceration is in the distribution of the posterior tibial artery, might you not have been able to improve your accuracy if you had sampled in a different location, either on the planar area or perhaps on the calcaneal skin?

Dr. Ballard. Definitely. There are a number of patients who had segmental $TcPO_2$ mapping of the foot. Forefoot and hindfoot measurements are instructive because one area may look good, whereas other areas look thoroughly dismal. For this study, we did not stratify treatment on the basis of segmented foot $TcPO_2$ levels.

Dr. Robert L. Kistner (Honolulu, Hawaii). In our use of the $TcPO_2$ we've found that the placement of the probe is critical and have had some confusion of how close to the ulcer to place the probe, and how to handle the edematous foot.

Could you give us some remarks about where that should be placed? Specifically, should it be placed at the point where you would expect the optimal flow at the mid foot or beyond, or should it be placed nearer the diseased location?

Dr. Ballard. Our vascular technicians are very knowledgeable with regard to $TcPO_2$ probe placement. We try to choose the most fleshy part of the forefoot, usually between the great and second toe. At times this can be difficult, especially in patients who have toe amputations or cellulitis present on the forefoot. We do not place the probe over either a tendon or a bony prominence because the readings may not be reliable.

Dr. Stephen C. Nicholls (Seattle, Wash.). I appreciate this kind of data because we have transcutaneous oxygen measurements in the laboratory, and I always believe that there's a certain amount of gestalt to it. Anything more than 20 raises your level of optimism. So we don't necessarily use a cutoff of 30 mm Hg, although, at less than 20 mm Hg it's usually impossible to get any healing.

I think there's a very distinct group of these neuropathic ulcers that are not only calcaneal but can also be tarsal ulcers and are usually due to changes in proprioception on weight bearing with or without a major ischemic component. We've seen patients with palpable foot pulses with major neuropathic ulcers whose transcutaneous oxygen is very high, and it becomes more a case of making sure that infection is not present and of orthotic management.

One thing we have done, and it's been done purely on an empiric basis, is to take two measurements, one distal at the base of the toes and one fairly proximal, in other words, either side of the cutting line for a transmetatarsal amputation. I wonder if you had any experience with this because for us it's been reasonably helpful to decide whether a transmetatarsal amputation is going to heal.

Dr. Ballard. As a routine, we did not segmentally map the foot. In our current algorithm, we are measuring both forefoot and hindfoot $TcPO_2$ levels.

Dr. Jerry Goldstone (San Francisco, Calif.). Did you say that only 48% of the patients with a low $TcPO_2$ had an abnormal angiography result?

Dr. Ballard. Ninety-six percent of patients with a low $TcPO_2$ level had an abnormal arteriography result. The overall accuracy of a palpable pedal pulse in predicting ultimate wound healing was 65%, whereas the accuracy of a transmetatarsal $TcPO_2$ level at 30 mm Hg or greater was 90%.