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Case Report

The Utilization of Transcutaneous Oxygen Pressures to Guide Decision-Making for Spinal Cord Stimulation Implantation for Inoperable Peripheral Vascular Disease: A Report of Two Cases

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Spinal cord stimulation (SCS) may be helpful in treating pain and vascular insufficiency associated with inoperable peripheral vascular disease (PVD). Often decision-making regarding progression from trial to implantation is based on subjective measures. Transcutaneous oxygen pressure, a measure of microcirculation and tissue perfusion, provides information on changes that may occur in PVD patients that undergo SCS trials and may provide predictive information for patient outcomes. This article reports on 2 patients with severe PVD in which transcutaneous oxygen pressures were measured during the trial phase, guided progression to implantation, and were followed in the postoperative period. Transcutaneous oxygen pressure values continued to improve following permanent implantation. We provide a review on transcutaneous oxygen pressure monitoring, along with emphasis on the technical aspects of transcutaneous oxygen pressure monitoring and its incorporation into practice. The decision to implant a SCS should be based on not only subjective measures of improvement, but also objective measures of improvement in transcutaneous oxygen pressure. Additional research is warranted to develop transcutaneous oxygen pressure predictive indices to assist in the selection of patients for progression to permanent implantation.

Key words: Spinal cord stimulation, peripheral vascular disease, transcutaneous oxygen pressure monitoring.

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Lower extremity peripheral vascular disease (PVD) affects approximately 8 million individuals, with more than 60,000 amputations performed yearly in the United States (1,2). Ischemic pain with PVD can be difficult to treat with medication. Spinal cord stimulation (SCS) is extensively used in Europe for inoperable PVD for both its ability to improve pain control and microcirculation; yet, it has not been widely used in United States (3). Transcutaneous oxygen pressure, a measure of microcirculation and tissue perfusion, may be useful in predicting success with

permanent implantation. We report 2 cases in which transcutaneous oxygen pressure monitoring was used to guide decision-making for SCS implantation for inoperable PVD. Also, we provide a description of the technical aspects of transcutaneous oxygen pressure monitoring and how to incorporate it into practice.

Case Reports

Case 1

An 81-year-old male with bilateral (left more symptomatic than right) lower extremity inoperable PVD, Fontaine Class 3 (Table 1), was referred for SCS.

Table 1. *The original Fontaine classification.*

Stage	Symptoms
I	Asymptomatic
II	Intermittent claudication
II-A	Pain-free, claudication with walking >200 m
II-B	Pain-free, claudication with walking <200 m
III	Rest and/or nocturnal pain
IV	Necrosis and/or gangrene

Past medical history included severe coronary artery disease (CAD) and multivessel PVD. Past surgical history included 2 left leg PVD surgeries (femoral-femoral graft and femoral-popliteal graft). The patient reported severe left leg and vascular claudication pain unresponsive to medication. A magnetic resonance angiogram demonstrated severe PVD with occlusion of the proximal left common iliac artery and attenuated flow in the left thigh with no major vessel runoff to the left foot. Prior to the SCS trial, transcutaneous oxygen pressures were measured in mmHg with the TCM400 (Radiometer, Copenhagen, Denmark) in the supine position (left 40, right 36) with the electrode at a constant temperature of 44°C on the dorsum of the respective foot. Readings were made at a room temperature of 21°C. The transcutaneous oxygen pressure monitor is shown in Fig. 1. During the trial, a percutaneous octad lead was inserted via the left paramedian approach at L1-L2 with the tip at the T9-T10 interspace to the left of midline. Transcutaneous oxygen pressure measurements (Fig. 2) were repeated after a 5-day trial with 30% and 36% improvements in the left and right leg, respectively. The patient reported greater than 75% pain relief and increased ambulation distance. Based on the improvements in transcutaneous oxygen pressure and in pain scores, a decision was

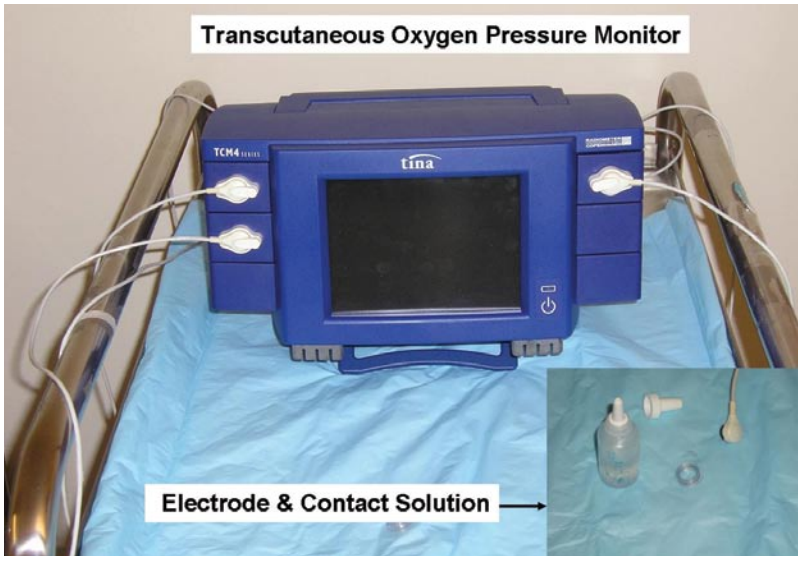

Fig. 1. *The transcutaneous oxygen pressure monitor, TCM400 (Radiometer, Copenhagen, Denmark), with electrode and contact solution.*

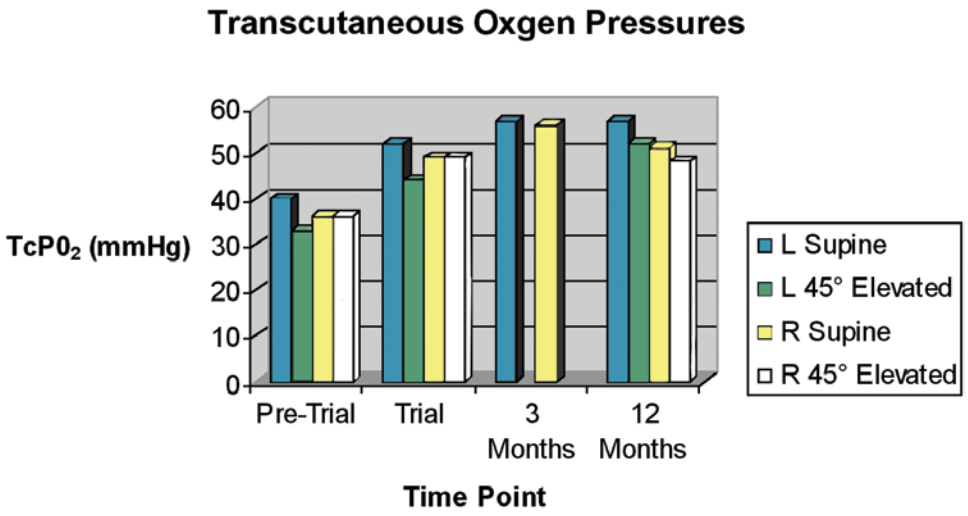

Fig. 2. *Supine position transcutaneous oxygen pressure values for the right and left lower extremity at different time points for Case 1. Forty-five degree elevated data were not measured at 3 months.*

made to progress to permanent implantation with an octad lead and a rechargeable generator (Medtronic Inc., Minneapolis, MN). At 12 weeks postoperatively, the transcutaneous oxygen pressures demonstrated a 43% and 56% improvement from baseline in the left and right leg, respectively. During the trial and permanent implant stage, he was instructed to keep the stimulator on continuously. The pain numerical rating scale (NRS) score for his left leg decreased from a 10/10 pre-insertion to a 0/10 post insertion. At 12 months postoperatively the improvement in left leg transcutaneous oxygen pressure persisted. Mechanical and cold allodynia resolved in his left leg. His claudication distance increased 6 fold. At 19 months postoperatively the patient continues to have greater than 50% to 75% reported pain relief (NRS 3–5/10).

Case 2

A 77-year-old female with Fontaine Class 4 severe, unilateral, inoperable PVD of the right leg, was referred for SCS. Past medical history was significant for CAD. Past surgical history included multiple PVD interventions for the right lower extremity including 1) right femoral-tibial bypass, 2) transluminal stent placement, and 3) right tibial and popliteal artery thrombectomy/arthrectomy/angioplasty. The patient's blood supply continued to become jeopardized, and an angiogram demonstrated total occlusion of the superficial femoral artery, popliteal artery, common tibial peroneal trunk, and proximal peroneal and posterior tibial arteries. The anterior tibial artery reconstituted above the ankle, but the peroneal and posterior tibial arteries did not reconstitute. Rest pain was 10/10 on a zero to 10 NRS. She had difficulty with ambulation secondary to pain that was resistant to medication. Her leg was pigmented and had a nonhealing ulcer measuring 1 cm wide, 1 cm long, and 1 mm deep above the right medial malleolus. This existed for approximately 12 months. She had undergone multiple debridements in an effort to encourage healing.

Prior to the SCS trial, transcutaneous oxygen pressures were measured in mmHg, in both the supine (left 72, right 34) and 45° elevated (left 58, right 18) positions with the electrode at 44° C on the dorsum of the respective foot at a room temperature of 21° C. Her right leg was classified with severe hypoxic syndrome with transcutaneous oxygen pressure marginal for wound healing and too low for hyperbaric oxygen treatment. Although the patient's Ankle Brachial Index was 0.71 in her left leg, she did not report pain or claudication. An Ankle Brachial Index could not be obtained for the right leg due to the severity of her disease. A percutaneous octad lead was inserted with a right paramedian approach at L2-L3 and placed with the tip at the inferi-

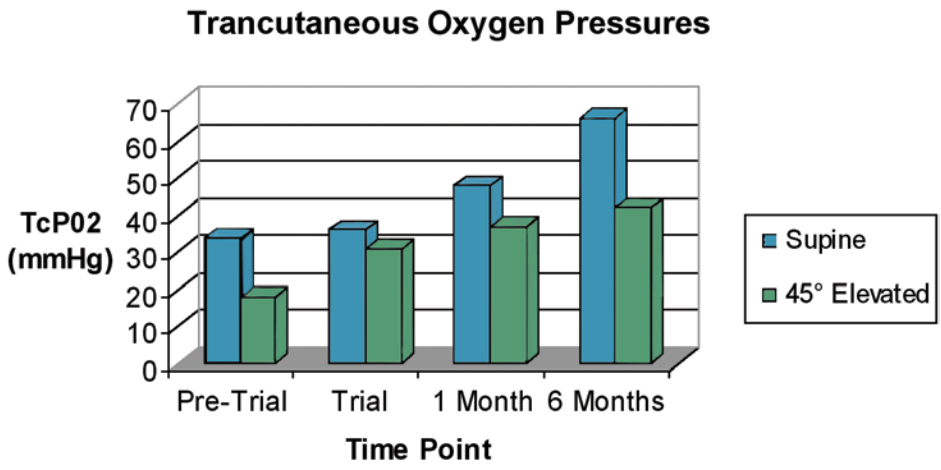

Fig. 3. *Supine and 45° elevated position transcutaneous oxygen pressure values for the right lower extremity at different time points for Case 2. A 16 mmHg decrease existed between the baseline (pre-trial) 45° elevated and the supine value positions.*

or border of the T10 vertebral body to the right of midline. The supine position transcutaneous oxygen pressures (Fig. 3) were repeated after a 5 day trial with a 6% improvement for the right leg. Notably, 45° elevated position transcutaneous oxygen pressure demonstrated a 72% improvement for the right leg from baseline. During the trial the patient reported greater than 50% pain relief with the NRS improving to 5/10 and increased ambulation distance. Based on her subjective improvement in pain and improvement in transcutaneous oxygen pressure in the elevated position, a decision was made to progress to permanent implantation with an octad lead with a rechargeable generator (Medtronic Inc., Minneapolis, MN). At 4 weeks postoperatively, the transcutaneous oxygen pressure in the right leg demonstrated an improvement from baseline of 41% in the supine position and 106% in the elevated position. The ulcer size had decreased to 3 mm wide, 4 mm long, and 1 mm deep. At 3 months the ulcer above her malleolus had healed. At 6 months, transcutaneous oxygen pressure continued to improve in the right lower extremity in the supine (47%) and elevated (133%) positions. The Ankle Brachial Index values did not change post implantation. At 11 months postoperatively, the patient reports greater than 70% pain reduction (current NRS 3/10), and a 55% reduction in her opioid usage. She is able to perform her activities of daily living including driving and walking.

Discussion

Treatment options for inoperable PVD with critical leg ischemia are limited. Often individuals progress to amputations that can result in increased energy expenditure (amputations increase oxygen consumption), reduction in life expectancy, psychological side effects, and inability to ambulate. Many amputations performed for patients with severe PVD are associated with poor wound healing secondary to depressed vascular inflow, nutrition, and immune status. Patients may develop phantom limb sensations. SCS is promising in some patients with non-reconstructable PVD shown by improved claudication distance, ulcer healing in ulcers ≤ 3 cm diameter (3,4) and possible limb salvage. The mechanism of efficacy for SCS in PVD is unknown, but several theories have been postulated including 1) modulation of the autonomic nervous system, 2) activation of the descending inhibitory system, 3) antidromic activation of sensory nerves (A-delta & C fibers) and subsequent release of vasodilator mediators (5,6).

Often the decision to implant a SCS for many pain conditions, after medical and behavioral assessments, is based on subjective scales of improvement. Subjective scales can be plagued by the health-care provider's and patient's expectations and by the placebo effect. Recently an N of 1 trial has been proposed as an aid

to decision-making prior to permanent SCS implantation for chronic pain states (7). We report 2 cases that highlight the effectiveness of using transcutaneous oxygen pressure. In PVD patients, monitoring and collecting transcutaneous oxygen pressure both pre-trial and post-trial may provide objective data on microcirculatory reserve to guide the decision to progress to implantation. Serial measurements in the follow-up period can provide additional information on the status of microcirculatory flow.

Transcutaneous oxygen pressure measurement was introduced for clinical use in the 1970s by Huch et al (8) in neonatal care units because of its correlation with arterial oxygen pressure. Transcutaneous oxygen pressure has been utilized in vascular and orthopedic settings because of its noninvasive characteristics and functional and physiologic assessment of skin and distal microcirculatory oxygen perfusion reserve. Transcutaneous oxygen pressure has been used to estimate healing potential of wounds, to diagnose level and degree of ischemia, to screen diabetic patients for feet at risk for ulcerations, to select amputation levels, to follow the results of revascularization procedures, and to assess the severity and progression of PVD (9). Misuri et al (10) demonstrated that amputations had an 85% failure rate when transcutaneous oxygen pressure values were less than 20 mmHg in the supine position at the selected level; thus, amputations should be performed at a more proximal level where blood flow is better. Patients for hyperbaric oxygen therapy for wound healing have been selected based on transcutaneous oxygen pressure (11,12). Decisions for hyperbaric oxygen therapy are based on both the absolute value and the relative change in value with certain provocative tests. Hyperbaric oxygen has been shown to be successful when values are greater than 40 mmHg in the supine position or when transcutaneous oxygen pressure increases by greater than 10 mmHg breathing 100% oxygen at 1 atm (13). Values less than 40 mmHg indicate significant vascular insufficiency that do not allow for wound healing with hyperbaric oxygen. Traditional measures of macrocirculation such as Ankle Brachial Indices and toe pressures are not sensitive to the changes in microcirucaltion and are not helpful in documenting changes in reserve that may occur with therapeutic interventions such as SCS (14).

The ability of transcutaneous oxygen pressure to assess microcirculation and therapeutic vascular reserve is defined by the relationship between the transcutaneous measurement of oxygen pressure and arterial oxygen pressure. The technical principle of transcutaneous oxygen pressure is based on the oxygen diffusion from red cells of cutaneous capillaries to the surrounding skin cells. A Clark electrode measures oxygen tension. A small amount of the oxygen that diffuses from the red cell will be utilized by the epidermal cells for metabolism. Therefore, the transcutaneous measurement of oxygen pressure will be slightly lower than values in the arteries. In healthy individuals transcutaneous oxygen pressure is approximately 0.8 times the arterial oxygen pressure (9). Based on multiple studies normal transcutaneous oxygen pressures have been estimated to be between 53 to 92 mmHg depending on measurement technique (15,16). Values of 40 mmHg clearly indicate suboptimal oxygen delivery and inadequately perfused tissue. Critical foot ischemia has been defined as less than 30 mmHg (17). Factors that can influence transcutaneous oxygen pressure values include 1) arterial oxygen pressure, influenced by cardiac and respiratory system function, 2) skin blood flow, 3) skin composition (i.e. thickness, edema, and capillarity), and 4) capillary temperature

Table 2. *Transcutaneous oxygen pressure measurement algorithm.*

Select site appropriately (area of interest & reference site)
Document site for standardization of future measurements
Place patient in the supine position
Standardize clinical conditions
Select electrode temperature
Prepare site
Calibrate and attach electrode
Initiate monitoring & allow values to stabilize
Record measurements
Perform provocative tests to further evaluate circulatory reserve
Analyze delta and absolute transcutaneous oxygen pressure values

Table 3. *Systemic and local factors that influence transcutaneous oxygen pressure measurements.*

Systemic	Local
Cardiac and pulmonary function	Skin thickness and bony prominences
Oxygen content	Edema
Vasoactive pharmacological substances	Tissue damage
Environment	Skin preparation
Central and peripheral vascular perfusion	Obesity

under the sensor. Major factors that influence transcutaneous oxygen pressure are arterial oxygen pressure and peripheral blood flow (9). A low transcutaneous oxygen pressure value mainly can be interpreted as a reduced arterial oxygen pressure either from cardiopulmonary disease or secondary to reduced central and regional blood flow.

Specific steps must be followed to optimize transcutaneous oxygen pressure measurements (Table 2). It is important to stabilize clinical conditions which can influence readings including setting ambient room temperature to 21–23° C (70 – 73°F) and avoiding smoking and caffeine use for at least 2 hours. Systemic and local factors also influence measurements (Table 3). A reference site is chosen, usually the second intercostal space, which represents tissue oxygen levels near the heart where little disturbance in blood flow is expected. In leg measurements, the dorsum of the foot is utilized. The skin on the plantar aspect of the foot is thicker and blood vessels are not as close to the skin. The electrode should be placed on an area of intact skin after removal of hair and dry epidermal cells. Areas of edema, large veins, and bone should be avoided. Subsequent measurements should be made at the same location. The electrode is heated to 44° C in order to change the structure of the stratum corneum and to shift the oxygen dissociation curve to the right, enhancing the diffusion of oxygen and increasing skin permeability allowing tissue oxygen to closely reflect arterial supply (11). Measurements are not collected until after 15–20 minutes when values have stabilized. Additional provocative maneuvers can be performed, such as leg elevation between 30° to 45° for 3 minutes, and transcutaneous oxygen pressure measurement repeated. These tests can be helpful in further assessing macro and micro circulatory capacity, especially in patients with ambiguous values in the supine position. Transcutaneous oxygen pressure values decrease with leg elevation. Bacharach et al (18) demonstrated that when the decrease is greater than 10 mm Hg in the elevated position for patients with baseline supine values between 20 to 40 mmHg, 80% of wounds will not heal. The total test takes approximately 40 minutes.

The interpretation of transcutaneous oxygen pressure values to guide SCS implantation has been suggested in European studies (14,19-21). Based on a randomized controlled trial, Claeys and Horsch (21) suggested Fontaine 4 individuals with baseline transcutaneous oxygen pressure values of less than 10 mmHg had a lower likelihood of responding to SCS for ulcer healing at 12 months and had higher amputation rates. If the absolute value rose to 26.0 ±8.6mmHg after SCS treatment, patients were typically able to heal ulcers. Horsch et al (20) in a retrospective study suggested that baseline transcutaneous oxygen pressure may be a useful predictor of treatment outcome with SCS regarding limb survival and prediction of future major amputation. Patients with baseline transcutaneous oxygen pressure measurements of less than 10 mmHg had lower levels of limb survival and higher rates of major amputation than patients with baseline values of 10–30 mmHg. Furthermore, in both groups successful treatment was seen in patients whose transcutaneous oxygen pressure values were greater than 30 mmHg post implantation. In patients with low baseline values, transcutaneous oxygen pressure increased gradually over the treatment duration (even at 18 months), whereas those with medium transcutaneous oxygen pressure values (10–30 mmHg) increased mainly in the first month. In the Dutch multicenter randomized control trial (22) there is a suggestion for reduced amputation rates in patients with transcutaneous oxygen pressure values that reach 10–30 mmHg. Amann et al (19) suggested those patients with transcutaneous oxygen pressure

values from 10 to 30 mmHg or those with transcutaneous oxygen pressure of less than 10 mmHg that increased during at least a 72 hour trial to 20 mmHg showed an increase in cumulative limb survival when treated with SCS.

Petrakis and Sciacca (14) utilized transcutaneous oxygen pressure measurements in the SCS testing period for diabetic patients with critical limb ischemia. Diabetic patients were selected because peripheral autonomic neuropathy may limit microcirculatory reserve response to SCS. A 20% increase in baseline transcutaneous oxygen pressure values during a 2-week trial served as a positive predictive index for successful therapy. SCS treatment failed in patients that did not show an increase in transcutaneous oxygen pressure values during the test period even if high pre-implantation baseline transcutaneous oxygen pressure values existed. It was suggested that most of the improvement in transcutaneous oxygen pressure values occurred in the first 2 weeks with limited subsequent improvement.

The cases reported here both had improvements in transcutaneous oxygen pressure values during a 5-day trial. In the Case 2 the improvement was small in the supine position (only 6%) because of the severity of the ischemia, but in the 45° elevated position the improvement was larger (77%). Here, the provocative maneuver provided additional information besides improvement in pain relief to base the decision to progress to permanent implantation. Based on her pretrial transcutaneous oxygen pressure she was not a candidate for hyperbaric oxygen treatment for a nonhealing wound. Based on her greater than 10 mmHg decrease in transcutaneous oxygen pressure with provocative testing pre-trial and the work of Bacharach et al (18), her likelihood of wound failure with amputation would be greater than 80%. Seen in Case 2, a nonhealing wound that was treated multiple times previously healed with 3 months of SCS treatment. Although the first patient (Case 1) had bilateral lower extremity PVD, only one lead was implanted because the right leg had adequate macrocirculation and was asymptomatic. Transcutaneous oxygen pressure improved in the right leg even with a left paramedian lead. Transcutaneous oxygen pressure demonstrated improvement that persisted at 12 months in Case 1 and at 6 months postoperatively in Case 2. Our data is in agreement with Amann et al (19) and Claeys and Horsch (21), but not Petrakis and Sciacca (14) who suggested significant improvement does not continue to occur after the trial period. Currently, the use of SCS for the treatment of inoperable PVD is not FDA approved.

Conclusion

SCS maybe an effective treatment for patients with inoperable PVD and should be considered in the treatment algorithm. Besides improvement in analgesia, transcutaneous oxygen pressure measurements may be useful in the trial and postoperative phase to objectively measure changes in microcirculation with emphasis on the absolute and delta values. Traditional measures of macrocirculation cannot be used to quantify the vascular effects (e.g. ABI). Here, we demonstrate 2 cases where improvements occurred in transcutaneous oxygen pressure during a 5-day trial which persisted and continued in the postoperative period. In patients with severe PVD, provocative maneuvers with transcutaneous oxygen pressure measurement may help to identify a microcirculatory reserve. Due to the expense and risks associated with SCS in a vulnerable patient population with multiple medical comorbidities, objective data of improvement during the trial stage is helpful to select patients. If notable increases in transcutaneous oxygen pressure are not seen, then perhaps one should question improvements that will occur with permanent implantation, especially in diabetic patients with autonomic neuropathy. Transcutaneous oxygen pressure monitoring may assist in evidence-based approach for patient selection for SCS implantation for inoperable PVD. Research is warranted to define and refine transcutaneous oxygen pressure indices to guide decisions for progression to permanent implantation of SCS therapy with emphasis on oxygen tension cut off and delta values.

References

1. McDermott MM. The magnitude of the problem of peripheral arterial disease: Epidemiology and clinical significance. *Cleve Clin J Med* 2006; 73:S2-7.
2. Erdek MA, Staats PS. Spinal cord stimulation for angina pectoris and peripheral vascular disease. *Anesthesiol Clin North America* 2003; 21:797-804.
3. Huber SJ, Vaglienti RM, Huber JS. Spinal cord stimulation in severe, inoperable peripheral vascular disease. *Neuromodulation* 2000; 3:131-143.
4. Deer TR, Raso LJ. Spinal cord stimulation for refractory angina pectoris and peripheral vascular disease. *Pain Physician* 2006; 9:347-352.
5. Claeys LG, Berg W, Jonas S. Spinal cord stimulation in the treatment of chronic critical limb ischemia. *Acta Neurochir-Suppl* 2007; 97:259-265.
6. Tanaka S, Barron KW, Chandler MJ, Linderoth B, Foreman RD. Role of primary afferents in spinal cord stimulation-induced vasodilation: Characterization of fiber types. *Brain Res* 2003; 959:191-198.
7. Cepeda MS, Acevedo JC, Alvarez H, Miranda N, Cortes C, Carr DB. An N-of-1 trial as an aid to decision-making prior to implanting a permanent spinal cord stimulator. *Pain Med* 2008; 9:235-239.
8. Huch R, Huch A, Lubbers DW. Transcutaneous measurement of blood Po2 (tcPo2) – Method and application in perinatal medicine. *J Perinat Med* 1973; 1:183-191.
9. Iabichella ML, Melillo E, Mosti G. A review of microvascular measurements in wound healing. *Int J Low Extrem Wounds* 2006; 5:181-199.
10. Misuri A, Lucertini G, Nanni A, Viacava A, Belardi P. Predictive value of transcutaneous oximetry for selection of the amputation level. *J Cardiovasc Surg* 2000; 41:83-87.
11. Ratliff CR. TCOMs as a screening tool for hyperbaric oxygen therapy. *Plast Surg Nurs* 2000; 20:15-17; quiz 18-79.
12. Fife CE, Buyukcakir C, Otto GH, Sheffield PJ, Warriner RA, Love TL, Mader J. The predictive value of transcutaneous oxygen tension measurement in diabetic lower extremity ulcers treated with hyperbaric oxygen therapy: A retrospective analysis of 1,144 patients. *Wound Repair Regen* 2002; 10:198-207.
13. Harward TR, Volny J, Golbranson F, Bernstein EF, Fronek A. Oxygen inhalation--induced transcutaneous PO2 changes as a predictor of amputation level. *JVascSurg* 1985; 2:220-227.
14. Petrakis E, Sciacca V. Prospective study of transcutaneous oxygen tension (transcutaneous oxygen pressure) measurement in the testing period of spinal cord stimulation in diabetic patients with critical lower limb ischaemia. *Int Angiol* 2000; 19:18-25.
15. Dowd GS, Linge K, Bentley G. The effect of age and sex of normal volunteers upon the transcutaneous oxygen tension in the lower limb. *Clin Phys Physiol Meas* 1983; 4:65-68.
16. Dowd GS, Linge K, Bentley G. Measurement of transcutaneous oxygen pressure in normal and ischaemic skin. *J Bone Joint Surg Br* 1983; 65:79-83.
17. Bunt TJ, Holloway GA. Transcutaneous oxygen pressure as an accurate predictor of therapy in limb salvage. *Ann Vasc Surg* 1996; 10:224-227.
18. Bacharach JM, Rooke TW, Osmundson PJ, Gloviczki P. Predictive value of transcutaneous oxygen pressure and amputation success by use of supine and elevation measurements. *J Vasc Surg* 1992; 15:558-563.
19. Amann W, Berg P, Gersbach P, Gamain J, Raphael JH, Ubbink DT. Spinal cord stimulation in the treatment of non-reconstructable stable critical leg ischaemia: Results of the European Peripheral Vascular Disease Outcome Study (SCS-EPOS). *Eur J Vasc Endovasc Surg* 2003; 26:280-286.
20. Horsch S, Schulte S, Hess S. Spinal cord stimulation in the treatment of peripheral vascular disease: Results of a single-center study of 258 patients. *Angiology* 2004; 55:111-118.
21. Claeys LG, Horsch S. Transcutaneous oxygen pressure as predictive parameter for ulcer healing in endstage vascular patients treated with spinal cord stimulation. *Int Angiol* 1996; 15:344-349.
22. Ubbink DT, Spincemaille GH, Prins MH, Reneman RS, Jacobs MJ. Microcirculatory investigations to determine the effect of spinal cord stimulation for critical leg ischemia: The Dutch multicenter randomized controlled trial. *J Vasc Surg* 1999; 30:236-244.