

# Thermal Biofeedback For Claudication In Diabetes: A Literature Review and Case Study

James E. Aikens, PhD.

## Abstract

Temperature biofeedback (TBFB) is designed to alter cutaneous temperature in treated extremities by providing information corresponding to minor temperature fluctuations in the context of therapeutic structure and reinforcement. Toe TBFB may improve vascular flow and walking tolerance in patients with peripheral vascular disease. This case study documents improved walking in a diabetes patient with lower extremity complications, and suggests TBFB might increase lower extremity temperature and blood flow volume pulse in uncomplicated diabetes. Ankle-brachial index (ABI) and walking function were assessed in a 60-year-old woman with type 2 diabetes and intermittent claudication, before and after five sessions of TBFB applied to the ventral surface of the great toe. Toe temperature increased during feedback phases but not during baseline phases. Improvements were seen in ankle-brachial index, walking distance, walking speed, and stair climbing. This case indicates the need for extended and controlled study of TBFB for improved vascular and ambulatory function in diabetic claudication.

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## Introduction

Intermittent claudication, in which leg muscle ischemia is elicited by mild ambulation, is one of the most debilitating clinical symptoms of peripheral vascular disease (PVD). The pain usually concentrates in the calves, precludes further walking, and only improves with rest. PVD is twenty times more common in diabetes patients than in age- and gender-matched controls,<sup>1,2</sup> is a robust independent predictor of lower extremity ulceration,<sup>3</sup> and is associated with vastly increased risk of amputation<sup>4,5</sup> and mortality.<sup>6</sup> Due to ambulatory limitations and intermittent pain, claudication can also be expected to significantly diminish quality of life for affected individuals.<sup>7,8</sup> Inactivity secondary to pain may increase risks for depression (which is already increased in diabetes)<sup>9,10</sup> and macrovascular disease,<sup>11,12</sup> and reduce glycemic control. Pentoxifylline is the only approved anti-claudication drug in the United States, but it has demonstrated only modest effects on improving treadmill performance.<sup>6</sup> Additional management strategies include smoking cessation and physical therapy. Although vascular surgery is an option, there is a high incidence of five-year mortality in diabetes following vascular surgery for claudication.<sup>13</sup> Many people with diabetes are ineligible for surgery because their claudication

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James E. Aikens, PhD - Assistant Professor of Clinical Psychiatry and Director, Behavioral Medicine Service, Department of Psychiatry, University of Chicago Hospitals.

Correspondence address: 5841 S. Maryland, MC-3077, Chicago, IL 60637-1470, USA. e-mail: jaikens@yoda.bsd.uchicago.edu

is not severe enough to justify the risk of surgery, or their disease affects arteries with inoperably small calibers.

Biofeedback is a behavioral procedure capable of directly altering physical function. Generally speaking, biofeedback involves the use of electronic equipment to monitor a visceral, somatomotor, or central nervous system function. Activity is then transduced, amplified, and “fed back” to the person as an auditory and/or visual signal. Delivered with appropriate reinforcement for changes in the desired direction, successful biofeedback increases voluntary control over monitored responses by teaching patients to manipulate the displayed signals.<sup>14,15</sup> Usually the targeted function falls below the patient’s sensory threshold and is autonomically mediated (e.g., frontalis muscle activity, heart rate, respiration rate, galvanic skin response, or blood flow). In temperature biofeedback (TBFB), skin temperature is monitored by means of a thermistor fastened on the fingertip pad or other relevant site. Because cutaneous temperature is closely linked to capillary flow, successful TBFB alters blood flow. Although typically applied to the finger, TBFB-trained warming responses have been documented in the foot,<sup>16,17</sup> earlobe, and abdomen.<sup>18</sup> Autogenic training is a related technique, often provided as an adjunct to TBFB, in which the patient receives direct verbal suggestions to experience specific targeted physical sensations.

Positive results of autogenic training (without TBFB) were reported in an uncontrolled study of 38 PVD patients with intermittent claudication and/or toe coldness, 60 percent of whom also had diabetes.<sup>19</sup> All subjects received training, which resulted in an average increase in toe skin temperature of 2.7°F and average increase in capillary flow velocity of 163 percent. Sixty-five percent of those subjects with diabetes reported at least a “considerable” decrease in claudication severity and/or foot coldness. Standardized

walking assessment was not conducted to verify self-reported claudication improvements.

In the only controlled study on biofeedback and claudication, 11 PVD patients (none with diabetes) were randomized to a control group or 32 sessions of progressive muscle relaxation training and multiple biofeedback modalities: frontalis EMG during initial training, followed by finger and toe TBFB, respectively.<sup>20</sup> At baseline, no subjects could walk more than 0.2 miles. After treatment, five of six subjects in the treatment group were completely free of claudication during a 30-minute, 1.125-mile treadmill re-evaluation, reflecting a ten-fold mean increase in walking distance. Improvement in claudication was accompanied by reduced resting and post-exercise brachial systolic blood pressure, and increased exercise ankle blood pressure, suggesting resistance dropped in the collateral vessels surrounding the occlusion. Actual skin temperature data were not reported. All controls continued to demonstrate baseline rates of claudication, walking impairment, and vascular function.

Only one group study directly evaluated TBFB and autogenic training in diabetes patients, but it specifically excluded patients with PVD or neuropathy.<sup>21</sup> Forty subjects first monitored great toe temperature five times weekly for four weeks, before and after relaxing for 15-20 minutes without any specific training. All subjects then received one TBFB session, followed by continued home temperature monitoring and audiotape-assisted foot warming practice. The training tape primarily contained autogenic instructions, although additional relaxation methods were also incorporated. Both toe temperature and blood volume pulse during relaxation improved significantly more after intervention than after the control phase. Toe temperature increased an average of 3.4°F, mean toe blood volume pulse increased 9.5 units, and arm diastolic blood

**Table 1.** Walking impairment questionnaire data.

WIQ subscore <sub>a</sub>	Baseline	Post-TBFB
Walking impairment	0%	25%
Walking distance	8%	14%
Walking speed	11%	25%
Stair climbing	4%	8%

a. WIQ scores potentially vary between 0% (complete impairment) and 100% (no impairment)

pressure dropped significantly. This study demonstrated the feasibility of combined TBFB and autogenic training for increasing foot blood flow in diabetes patients without major lower extremity complications. However, the exclusion of those with PVD precludes generalization to the diabetes patient group that theoretically might benefit most.

Finally, a case report raised the possibility that such effects could extend to diabetes with lower extremity complications. Saunders et al<sup>22</sup> provided TBFB and autogenic training to a 48-year-old type 2 diabetes patient with symptomatic PVD, decreased bilateral toe sensitivity, and chronically cold feet. At baseline, the patient could not walk more than three blocks without resting, due to claudication. Intervention consisted of finger TBFB, followed by toe TBFB combined with autogenic and other relaxation training methods. Toe temperature change occurred during toe TBFB but not hand TBFB, and was +2.4°F within sessions, +0.3°F between sessions, and +3.8°F at 48-month follow-up. Claudication completely remitted by session 12, and daily walking distance increased to 3.5 miles following treatment and 4.5 miles at 48-month follow-up.

To summarize, TBFB may reduce pain and improve walking functions in PVD patients with and without diabetes. However, only a single case study documented foot warming and reduced claudication in diabetes

complicated by neuropathy and PVD. Although these findings are suggestive and encouraging, it is not currently clear whether TBFB can consistently raise cutaneous temperature and blood pressure in the lower extremities of diabetes patients with symptomatic PVD, and whether such changes translate into reduced claudication and improved walking ability.

This case study was performed in an attempt to replicate existing data and to provide an assessment of potential effects on leg vascular function.

## Methods

**Subject:** The subject was a 60-year-old, nonsmoking Caucasian female with type 2 diabetes mellitus of 17 years' duration. Her most recent glycosylated hemoglobin was 9.1 percent, assessed two weeks prior to the study. Diabetes complications and additional conditions included symptomatic PVD, hypercholesterolemia, hypertension (BP: 140/80), coronary artery disease with abnormal stress test, obstructive sleep apnea, and obesity. Medications were insulin 70/30, Cardizem CD 240 mg qd, one aspirin qd, Mevacor 20 mg qd, and vitamin B6 50 mg qd.

**Baseline data:** Significant right-sided lower extremity claudication at baseline was indicated by objective signs, including resting ankle-brachial index (ABI) of 0.68, and a bi-phasic Doppler waveform; and subjective symptoms of severe right calf pain triggered by walking 50 feet and inability to walk more than one city block. The Walking Impairment Questionnaire (WIQ)<sup>23</sup> was used to quantify claudication.

ABI is obtained by dividing the ankle systolic pressure by the brachial systolic pressure. An ABI of 1.0 or higher reflects normal functioning. ABI from 0.9-1.0 suggests asymptomatic (lower extremity) PVD; and ABI from 0.5-0.9 reflects symptomatic lower extremity claudication. An ABI below 0.5 is severe PVD.

**Table 2.** Results of TBFb intervention in claudication.

Session	Baseline (5 min. period)	Entire warming attempt	Final 5 min. of warming attempt	Temperature change <sub>a</sub>	t <sub>(9)</sub> <sub>b</sub>	sign. <sub>c</sub>
Preinterv.	87.87 (0.14)	87.84 (0.20)	87.90 (0.11)	+0.03 (0.08)	-1.32	.22
1	85.63 (0.12)	87.13 (0.81)	87.37 (0.66)	+1.7 (0.71)	-7.73	<.0001
2	88.37 (0.16)	89.56 (0.55)	90.18 (0.24)	+1.81 (0.27)	-20.97	<.0001
3	84.42 (0.18)	86.72 (1.17)	87.73 (0.17)	+3.31 (0.33)	-31.93	<.0001
4	87.40 (0.18)	89.25 (0.87)	89.96 (0.15)	+2.56 (0.17)	-46.50	<.0001
5	85.20 (0.13)	87.03 (1.08)	88.27 (0.11)	+3.07 (0.19)	-52.06	<.0001

- a. Mean (SD) of differences between 30-second epochs from baseline and final five minutes of warming attempt.
- b. Matched-samples t-test comparing baseline to last five minutes of warming attempt.
- c. Identical pattern of significance is obtained when the analysis compared either means or maximum temperatures from the baseline and entire warming period.

On this validated measure, respondents rate walking impairment secondary to calf (or buttock) pain/aching/cramping (1 item), difficulty ambulating various distances (7 items) and speeds (4 items), and difficulty climbing stairs (3 items). All responses are weighted and expressed as percentage of the maximum possible function, ranging from 0 percent (unable to perform any ambulatory activities due to claudication) to 100 percent (no impairment).

The subject's baseline WIQ responses indicated severe impairment due to claudication (see Table 1), with scores of 0 percent (impairment), 7.8 percent (distance), 11 percent (speed), and 4 percent (stair climbing).

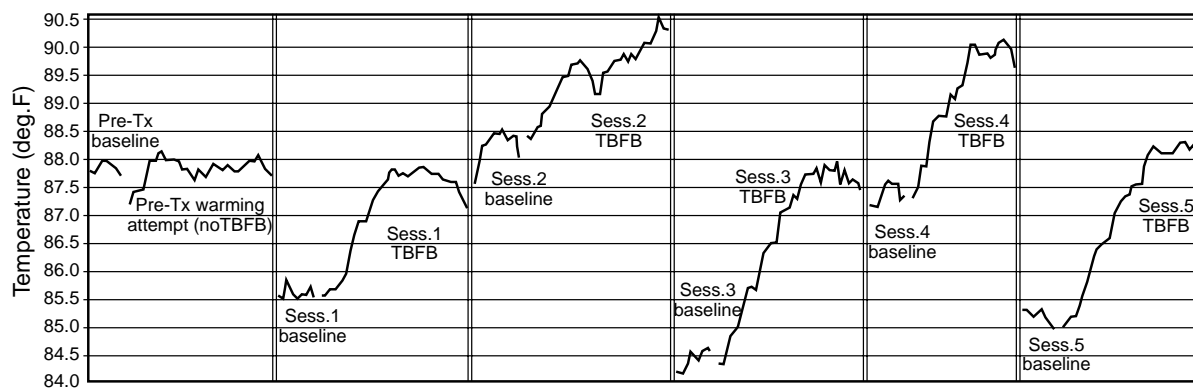
**Intervention:** TBFb intervention was provided by the author, a clinical psychologist experienced in biofeedback therapies. Equipment consisted of a J&J T-68 thermal biofeedback instrument with research-grade cutaneous thermistors, an I-330 computer interface, a Pentium 199 MHz computer with CRT and headphones providing graphical and auditory feedback, and DataTrack software (Expanded Technologies, Inc., Shreveport, LA, 1995) for data acquisition and biofeedback session management. Mean temperatures were computed across consecutive 30-second

epochs throughout the baseline and TBFb periods. Baselines were continued until temperature was stabilized for five consecutive minutes (as defined by standard deviation <0.5 across 10 epochs, with no two consecutive 30-second periods showing  $\geq 0.25^\circ\text{F}$  increase, and lack of any visible qualitative graphical warming trend). TBFb was then initiated for the next 18 minutes. Between sessions the subject was explicitly instructed to retain her usual walking habits, but was encouraged to apply any acquired foot warming skills before and during walking, especially if she experienced leg pain. She then received five weekly sessions consisting of one baseline and one TBFb phase, with the thermistor applied to the ventral surface of her right-side great toe pad. The subject was also instructed to practice any acquired foot warming skills at home, at least five times per week.

### Results

During an 18-minute pre-intervention warming attempt, the temperature of the subject's monitored toe remained stable and showed no obvious increasing or decreasing trend ( $p=0.22$ ), indicating the lack of obvious

**Figure 1.** Toe temperature of 60-year old female with diabetes and intermittent claudication



Note: Plotted data are means of 30-second intervals.

pre-existing foot warming skills. During all five TBFB phases, the subject demonstrated rapid and progressively larger temperature changes from baseline, ranging from  $+1.7^{\circ}\text{F}$  to  $+3.1^{\circ}\text{F}$  by the fifth session (all  $p$  values  $<0.0001$  for increases from same-session baseline). Session-by-session temperature data are presented in Table 2 and Figure 1.

The subject logged 18 home practice sessions, indicating a high home practice work compliance rate of 90 percent. Vascular reassessment indicated ABI improved to 0.75. It is noteworthy this increase, achieved in five 18-minute TBFB sessions, represented about half of the effect considered clinically significant. WIQ responses assessed after the fifth session (see Table 1) demonstrated improved scores on all scales, suggesting moderate functional improvements consistent with ABI change.

## Discussion

In summary, previous research suggests thermal biofeedback can be of potential therapeutic benefit in symptomatic peripheral vascular disease, or intermittent claudication, a common complication of diabetes mellitus. In this intervention trial, a subject treated with brief TBFB rapidly learned to increase the temperature of her treated toe subsequent to TBFB exposure. After five TBFB training sessions, she showed improvements in lower extremity

blood pressure, reported walking impairment, walking distance, walking speed, and stair climbing. The modification of ABI from 0.68 to 0.75, achieved in five 18-minute TBFB sessions, represents roughly half of the effect size (0.15) considered to be clinically significant. These findings suggest TBFB might be capable of enhancing vascular and ambulatory function in diabetic claudication.

Because of the brevity of the intervention period and the complaint of more severe claudication in the right leg, TBFB was only applied to the subject's right toe. It was interesting to note the lateral specificity of trained warming responses. Other data indicated while TBFB training of the index finger also resulted in warming of other fingers on the trained hand,<sup>24</sup> effects did not extend to the untrained contralateral hand,<sup>25</sup> and in the Saunders et al case,<sup>22</sup> the acquisition of fingertip warming skills did not necessarily lead to toe warming.

Two physiological mechanisms seem to underlie behaviorally-induced blood flow alterations.<sup>26</sup> Both TBFB and autogenic training are believed to reduce sympathetic alpha adrenergic stimulation and thus reduce vasoconstriction. It has also been proposed that fingertip vasodilation induced by TBFB occurs via non-neural activation of beta-adrenergic-mediated dilation of precapillary sphincters.<sup>27-29</sup>

## Conclusion

Subsequent research ought to confirm and extend these findings, using more subjects and randomized assignment to biofeedback versus conventional medical care alone. Applying more biofeedback sessions would help address an important dose-response question; i.e., are effects related to the amount of training received? Another objective of future work should be an increased emphasis upon transferring warming skills from the therapy setting to the real-world activities and environments where they are most needed. One possibility is that, by repeating the no-feedback control phase numerous times during intervention, therapists might help the patient to eventually warm the foot without biofeedback assistance, hopefully putting him or her in a better position to transfer their newly acquired warming skills to everyday natural circumstances.

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