



ACOUSTIC/MAGNETIC FIELD ASSISTED PERFUSION IN PERIPHERAL VASCULAR DISEASE

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Abstract: The goal of this study was to assess the effectiveness of an acoustic device combined with static magnetic fields on a cohort with peripheral vascular disease (PVD). The device the, Cyma[®] 1000, delivered five acoustic frequencies, 900- 1300 Hz, chosen for arterial support. The array of eight static magnets, seated in and around the diaphragm, were permanent neodymium magnets. The field strength of the magnets had a surface magnetic induction of 2000 Gauss peak or 200 mT. These static magnets produce a dynamic magnetic field that oscillates at the same frequency as the acoustic frequencies, inductively linking with the cell's own electromagnetic field. After the successful results of a prior study consisting of a control group, having normal perfusive ability, and a second group with a range of pathological conditions that included PVD, it was decided that a further study was warranted. Bilateral limb Thermography and manual pulse assessment by palpation of both dorsalis pedis pulses and posterior tibial pulses was used to monitor perfusion and pulsatile blood flow at baseline (baseline pulses were absent or greatly diminished in the entire cohort.) Thermography and pulse assessment were repeated after the application of the Cyma[®] 1000. All subjects under study showed a marked application improved perfusion indicated by Thermography. Dorsalis pedis pulses and posterior tibial pulses were also greatly improved. The previously absent pulses became palpable and in cases where palpable pulses were diminished, pulse quality was significantly improved. Follow-up Thermography also showed a significant decrease in inflammation in areas of inflammatory PVD, and a significant decrease in dependent edema as well.

Goal

The goal of this investigation, using Thermography and pulse assessment by palpation as an indicator, was to examine the value of the frequencies specific to arterial support in increasing arterial flow to areas where acoustic fields combined with dynamic static magnetic fields were applied.

Introduction

Vascular diseases of the extremities involve arteries, veins, and capillaries (vascular system) as well as the lymphatic system. PVD commonly develops as a result of atherosclerosis, or hardening of the arteries. Atherosclerosis is a progressive disease hallmarked by the development of vascular atherosclerotic lesions characterized by lipid accumulation, inflammation, cell death and fibrosis.¹⁻⁴ Atherosclerotic lesions can cause a limitation in blood flow due to the accumulation of plaque, inflammatory proteins, dead cells, waste products and tissue edema causing a fibrotic stenosis that leads to the lack of oxygen and nutrition in the tissues located distally to the lesion.

Peripheral vascular disease (PVD) is a very common condition affecting 12-20% of Americans age 50 and older. Although atherosclerosis is often thought to be a disease of 'middle age' or older, the development of atherosclerotic lesions are believed to begin in childhood. Epidemiological studies have identified numerous risk factors involved in the onset of atherosclerosis such as: environmental agents, genetic predisposition, hyperlipidemia, hypertension, diabetes mellitus, obesity, male sex, smoking, age, family history, physical inactivity, parasites and infections.^{4,5}

PVD's symptomatic presentation of intermittent claudication is characterized by leg pain that occurs when walking or exercising and disappears when activity ceases. Other symptoms of PVD include: numbness and tingling in the lower legs and feet, cold lower legs and feet, and ulcers or sores on the legs or feet that don't heal. The development of the atherosclerotic plaque initiates the process, progressing in severity and leading to intermittent claudication. The pathological progression to critical ischemia follows, with rest pain and gangrene. The basic underlying pathophysiological processes underlying these major complications of PVD are thrombosis and atherogenesis.⁶

PVD is associated with significant morbidity and mortality.⁶⁻⁹ It is a frequent cause of physician visits and hospitalizations. Emergency treatment is commonly required in this condition due to thrombosis of the affected arteries. Many victims of PVD also experience other cardiovascular sequeli, such as heart attacks and strokes.¹⁰ These pathological sequeli are the main causes of death in PVD.^{8,11} It carries a mortality rate of about 20% per year.¹²

The chronic inflammatory response of PVD in the walls of the arteries is a pathological condition characterized by the accumulation of macrophage white blood cells and promoted by low density lipoproteins. The concurrent active inflammation, tissue destruction, and attempts at repair cause the formation of multiple plaques within the arteries. Chronically inflamed tissue is characterized by the infiltration of mononuclear immune cells (monocytes, macrophages, lymphocytes, and plasma cells), tissue destruction, and attempts at healing, which include angiogenesis and fibrosis.

Adequate blood supply is vital to the health of all cells and organ systems and essential for sustaining life. The function of the circulatory system is to deliver oxygen and nutrients to all cells. It also removes carbon dioxide, waste products excessive water, ions as well as other molecules in the plasma to maintain optimal tissue pH. Since oxygen is mainly bound to hemoglobin in red blood cells, insufficient blood supply causes tissue to

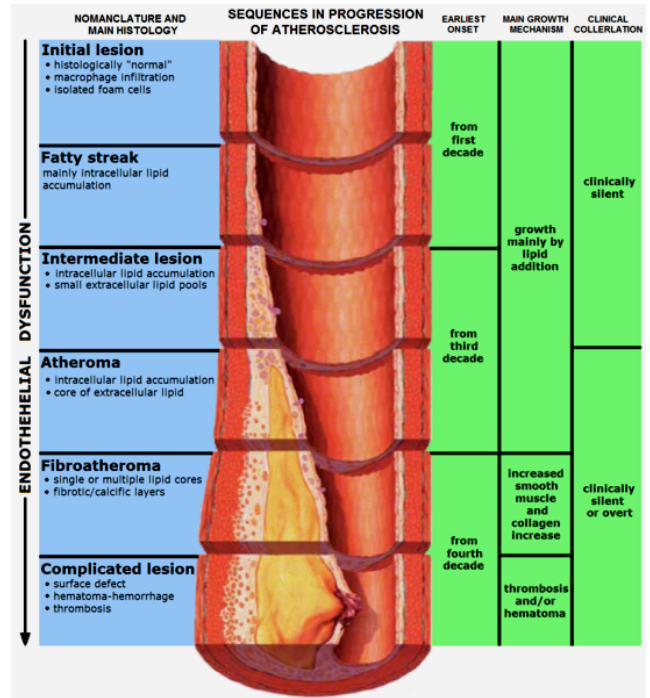


Illustration 1. Stages of endothelial dysfunction in atherosclerosis.

become hypoxic, or, if no oxygen is supplied at all, anoxic. Anoxia can cause necrosis (cell death). Without viable perfusion, organ systems suffer; the sequeli of ischemic cascade and cellular degradation ensues, thus life ends. When perfusion is impeded, the eschemic cascade ensues within seconds to minutes, necrosis due to ischemia usually takes about 10-12 hours.^{13,14}

Edema occurs due to leakage of large molecules like albumin from blood vessels through the damaged tissue. These large molecules pull water into the tissue after them by osmosis. This 'vasogenic edema' causes compression of and damage to tissue.

Over the past decade a number of studies have been performed to investigate the therapeutic use of magnetic fields to mitigate against ischemic cascade while it is occurring and to repair tissues damaged following reperfusion.^{15,16} A biological mechanism behind the efficacy of the magentic field in these cases may lie in the recent mathematical developments in understanding the self fields of the hydrogen atom.^{17,18} Self-field theory gives actual dynamics of the sub-atomic particles in contrast to probabilistic results of quantum mechanics. When a magnetic field is applied, the electron inside the atom does not change its orbital speed but rather its cyclotron speed, its spin, is increased. Like the gyroscopic ability well-known in ballistic design to keep projectiles on track and thus increase their effective range, the magnetic field may increase the ability of atoms and molecules to ward off unwanted randomly directed electric fields in the arterial milieu due to the ischemic cascade reactions described above. As for the acoustic fields, Bauer and Fleming have previously presented results from another pilot study using the Cyma 1000's acoustic fields without the dynamic magnetic field to promote repair of a tendon in a thoroughbred racehorse.¹⁹

Methods

After obtaining and reviewing a detailed medical health history and a medical examination; a group of 10 subjects, between the ages of 57 and 93, that had a history of PVD, was selected. The study cohort consisted of 6 female and 4 male subjects. One subject was eliminated from the study due to failure to save the Thermographic images to the computerized imaging program file. Baseline Thermographs and manual pulse assessments were obtained before any intervention. After evaluating the baseline thermographs and pulse assessments, the acoustic/magnetic device (Cyma[®] 1000) was used to deliver specific audible frequencies that ranged from 900 to 1300 Hz. These frequencies were administered for 15 minutes to the areas of pathology of anterior lower legs and feet, bilaterally. Informed consent was obtained from each candidate before their participation in this investigation.

The pulse assessments are based on a standard scale of 0-5. A non-palpable or absent pulse is represented by the number 0, whereas, a normal palpable pulse is represented by the number 5.

Results

Subject 1

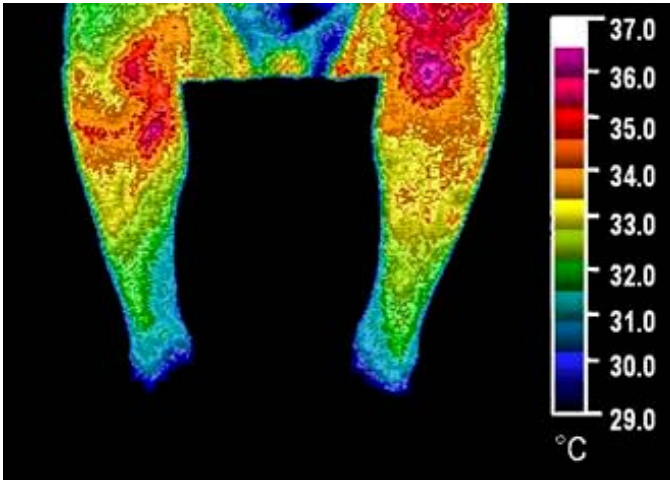


Figure 1a. Before

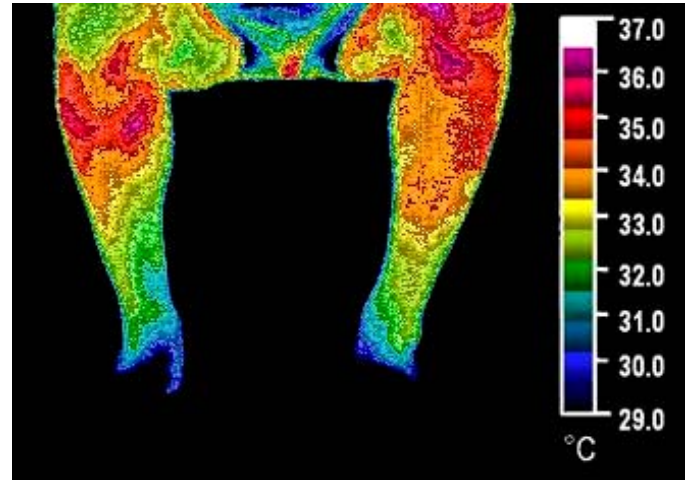


Figure 1b. After

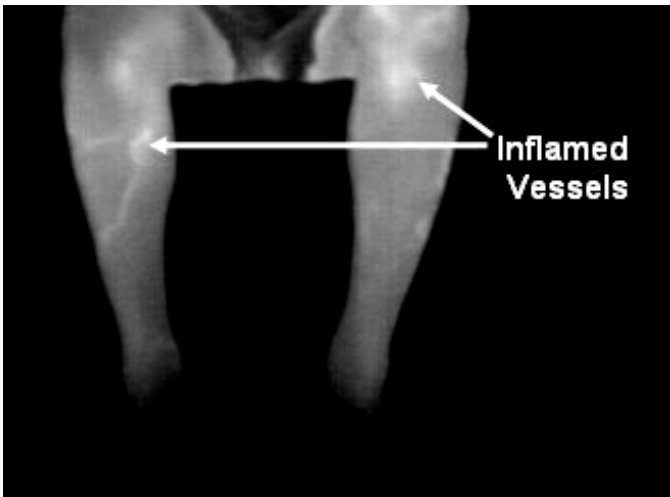


Figure 2a. Before

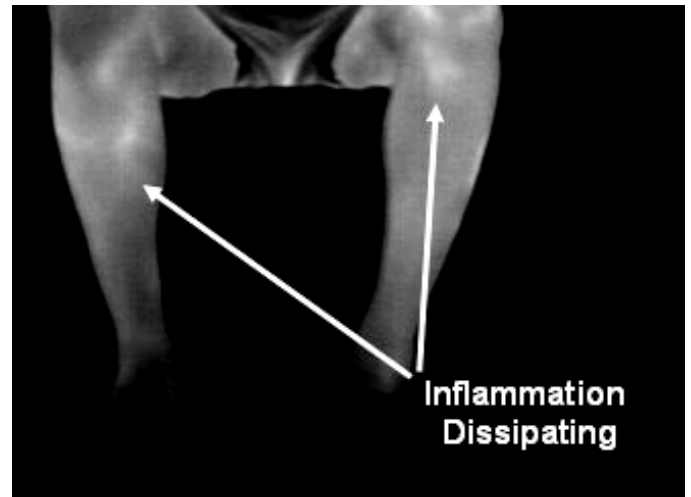


Figure 2b. After

Before	R	L
Post Tibial Pulse Quality	4	3
Pedal Pulse Quality	1	1

Table 1a. Before

After	R	L
Post Tibial Pulse Quality	5	5
Pedal Pulse Quality	2	2

Table 1b. After

In the Thermographic images above, Figures 1a and 2a, a marked inflammation, including inflammation of the blood vessels was shown before the application of the acoustic/magnetic field. In the followup Thermography, Figures 1b and 2b, a marked decrease in inflammation and an increase in perfusion was shown as evidenced by the concurrent improvement in both post tibial and pedal pulse quality shown in Table 1a as compared to Table 1b after the application of the acoustic/magnetic field.

Subject 2

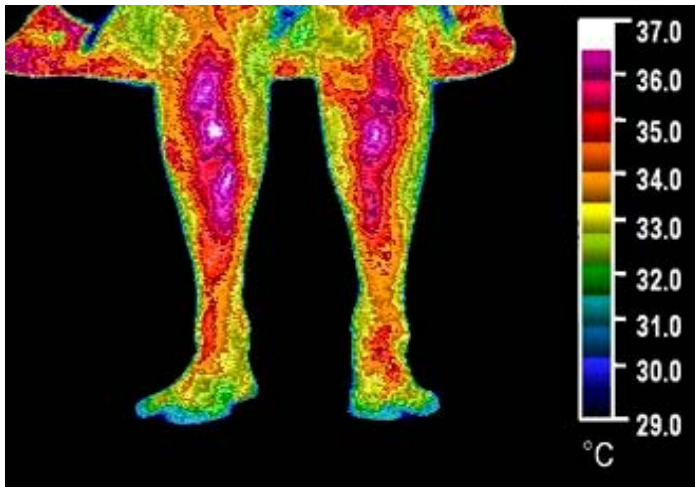


Figure 3a. Before

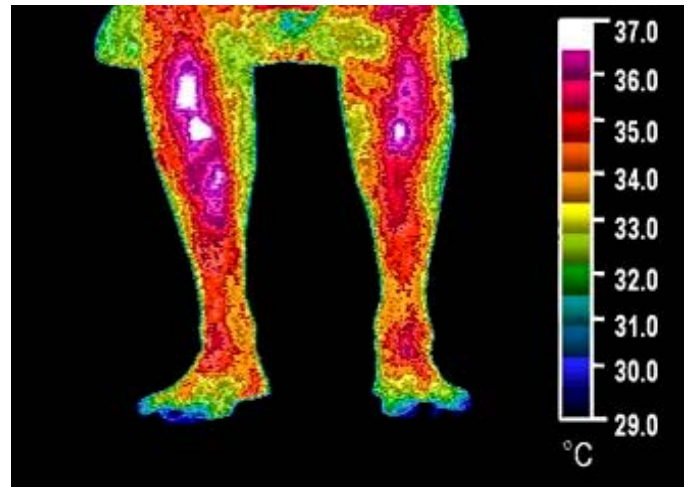


Figure 3b. After

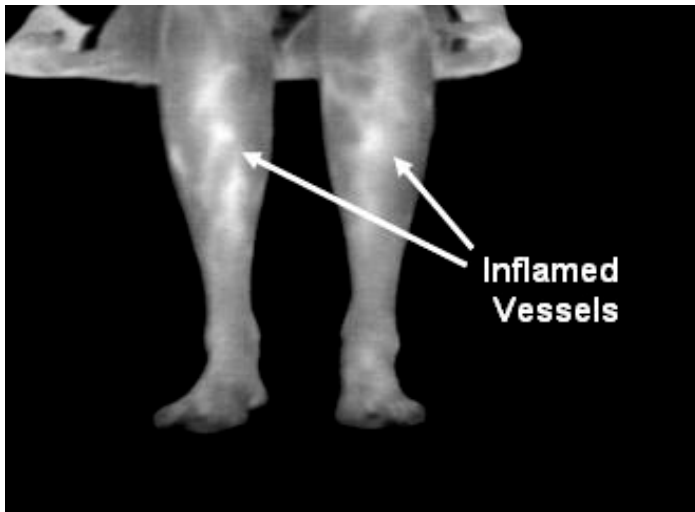


Figure 4a. Before

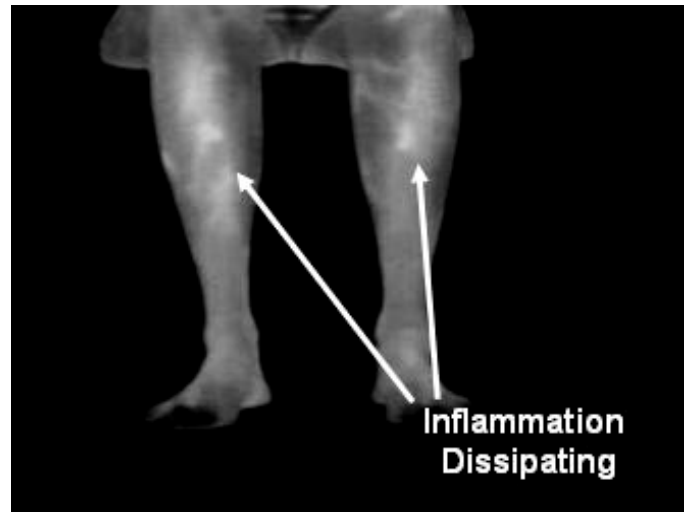


Figure 4b. After

Before	R	L
Post Tibial Pulse Quality	0	0
Pedal Pulse Quality	1	1

Table 2a. Before

After	R	L
Post Tibial Pulse Quality	2	5
Pedal Pulse Quality	3	5

Table 2b. After

In the Thermographic images above, Figures 3a and 4a, a marked inflammation, including inflammation of the blood vessels was shown before the application of the acoustic/magnetic field. In the followup Thermography, Figures 3b and 4b, a marked decrease in inflammation and an increase in perfusion was shown as evidenced by the concurrent improvement in both post tibial and pedal pulse quality shown in Table 2a as compared to Table 2b after the application of the acoustic/magnetic field.

Subject 3

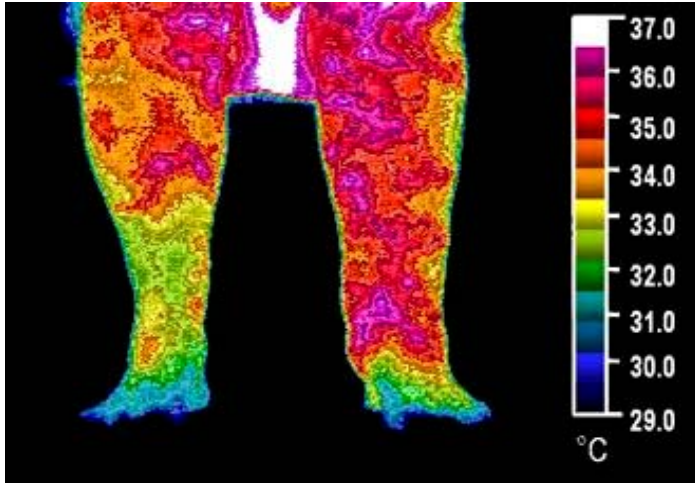


Figure 5a. Before

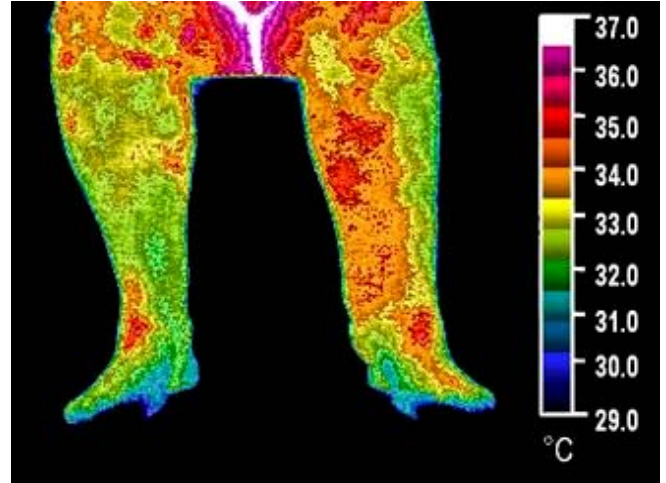


Figure 5b. After

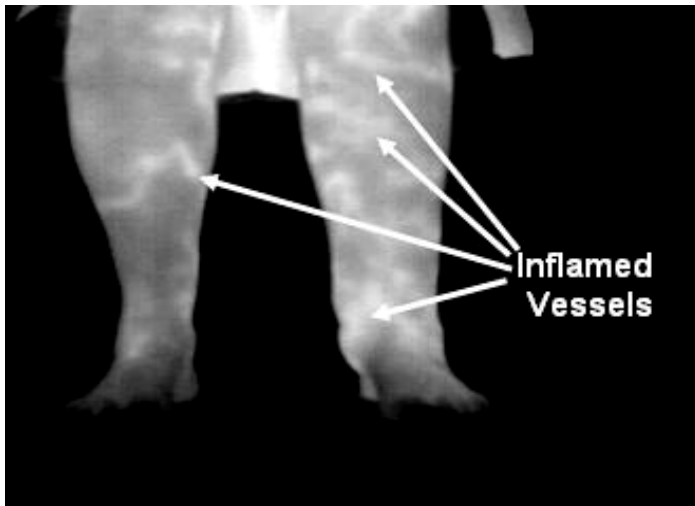


Figure 6a. Before

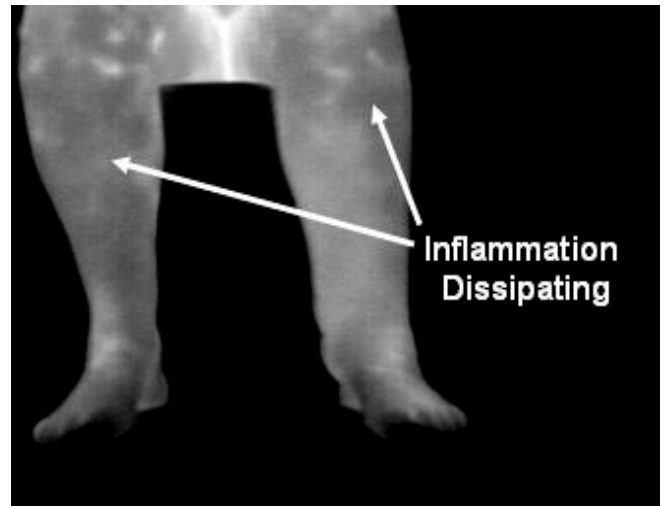


Figure 6b. After

Before	R	L
Post Tibial Pulse Quality	0	0
Pedal Pulse Quality	4	4

Table 3a. Before

After	R	L
Post Tibial Pulse Quality	1	1
Pedal Pulse Quality	5	5

Table 3b. After

In the Thermographic images above, Figures 5a and 6a, a marked inflammation, including inflammation of the blood vessels was shown before the application of the acoustic/magnetic field. In the followup Thermography, Figures 5b and 6b, a marked decrease in inflammation and an increase in perfusion was shown as evidenced by the concurrent improvement in both post tibial and pedal pulse quality shown in Table 3a as compared to Table 3b after the application of the acoustic/magnetic field. A marked decrease in edema, left leg greater than right, was shown as well.

Subject 4

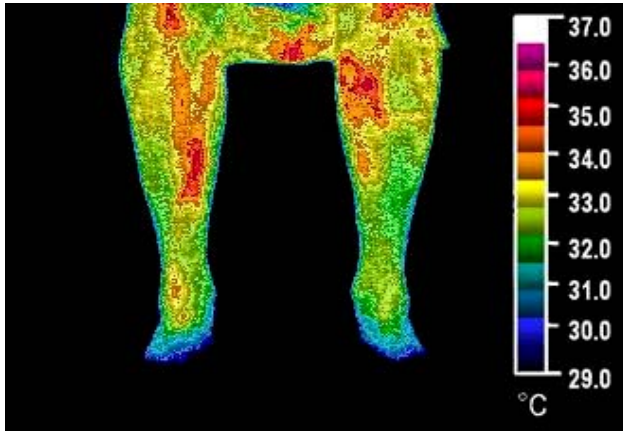


Figure 7a. Before

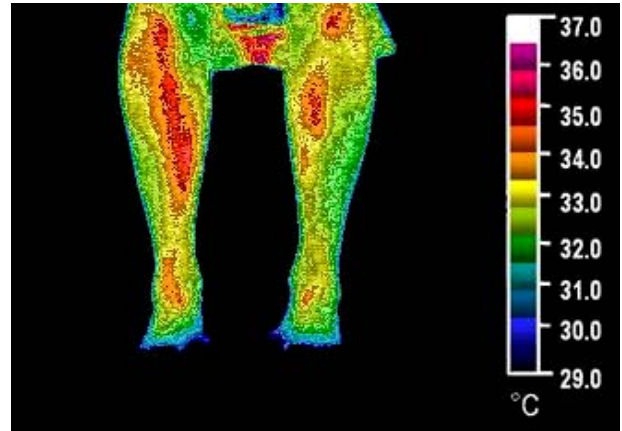


Figure 7b. After

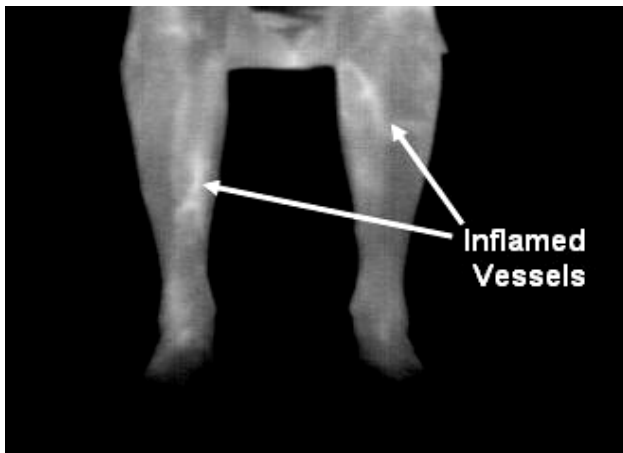


Figure 8a. Before

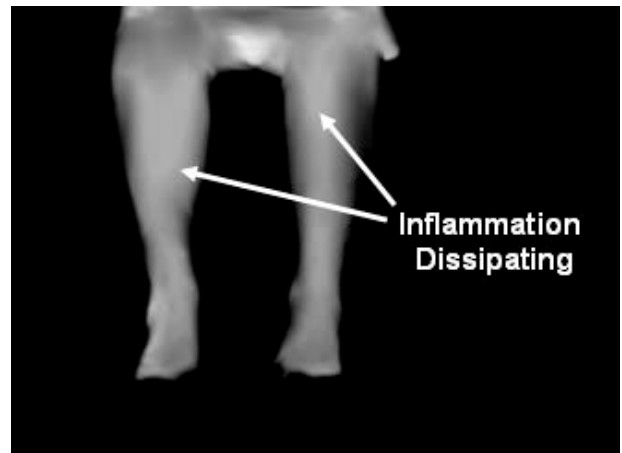


Figure 8b. After

Before	R	L
Post Tibial Pulse Quality	0	0
Pedal Pulse Quality	0	0

Table 4a. Before

After	R	L
Post Tibial Pulse Quality	1	1
Pedal Pulse Quality	1	1

Table 4b. After

In the Thermographic images above, Figures 7a and 8a, a marked inflammation, including inflammation of the blood vessels was shown before the application of the acoustic/magnetic field. In the followup Thermography, Figures 7b and 8b, a marked decrease in inflammation and an increase in perfusion was shown as evidenced by the concurrent improvement in both post tibial and pedal pulse quality shown in Table 4a as compared to Table 4b after the application of the acoustic/magnetic field. A marked decrease in edema, left leg greater than right, was shown as well.

Subject 5

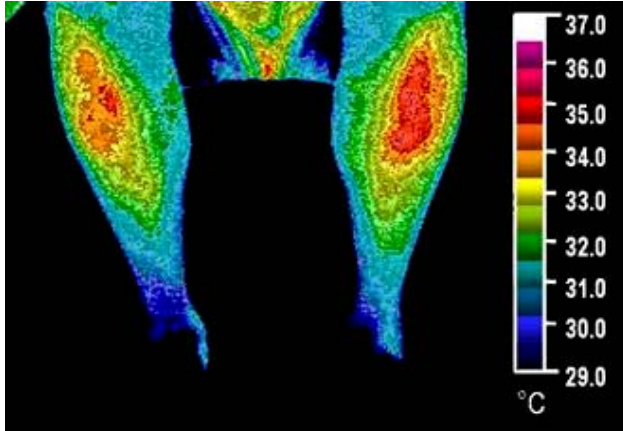


Figure 9a. Before

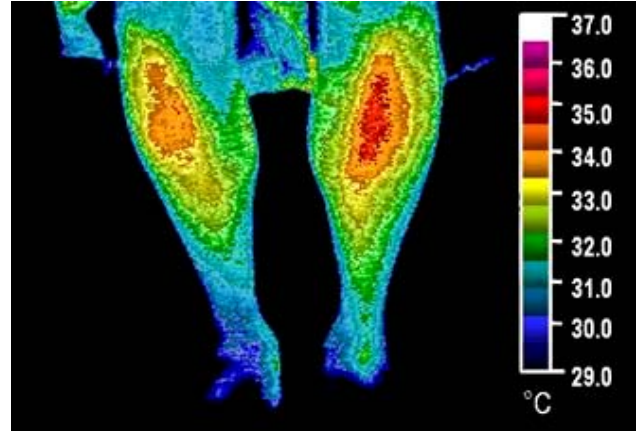


Figure 9b. After

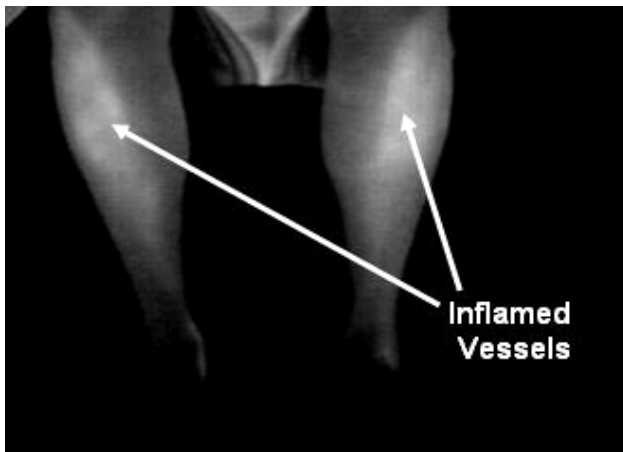


Figure 10a. Before

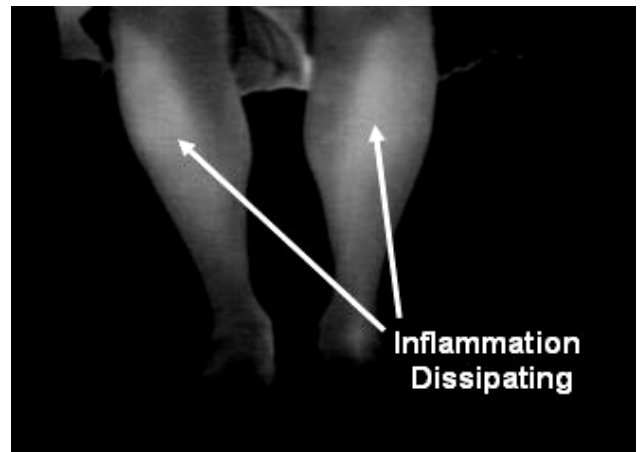


Figure 10b. After

Before	R	L
Post Tibial Pulse Quality	0	0
Pedal Pulse Quality	0	0

Table 5a. Before

After	R	L
Post Tibial Pulse Quality	1	1
Pedal Pulse Quality	1	1

Table 5b. After

In the Thermographic images above, Figures 9a and 10a, a marked inflammation, including inflammation of the blood vessels was shown before the application of the acoustic/magnetic field. In the followup Thermography, Figures 9b and 10b, a marked decrease in inflammation and an increase in perfusion was shown as evidenced by the concurrent improvement in both post tibial and pedal pulse quality shown in Table 5a as compared to Table 5b after the application of the acoustic/magnetic field.

Subject 6

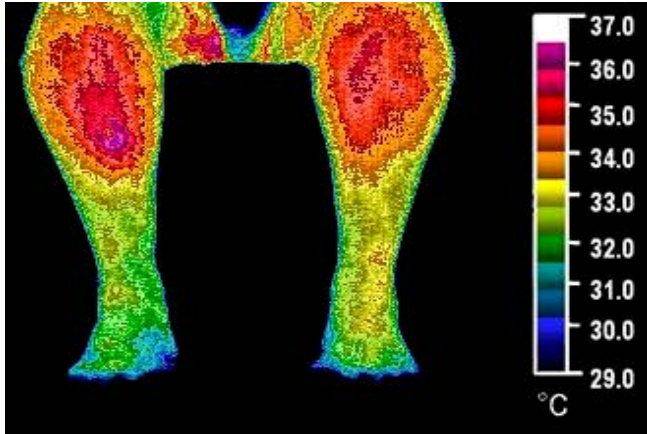


Figure 11a. Before

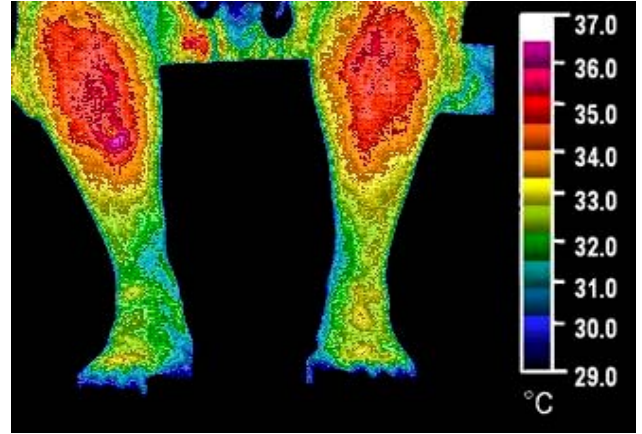


Figure 11b. After

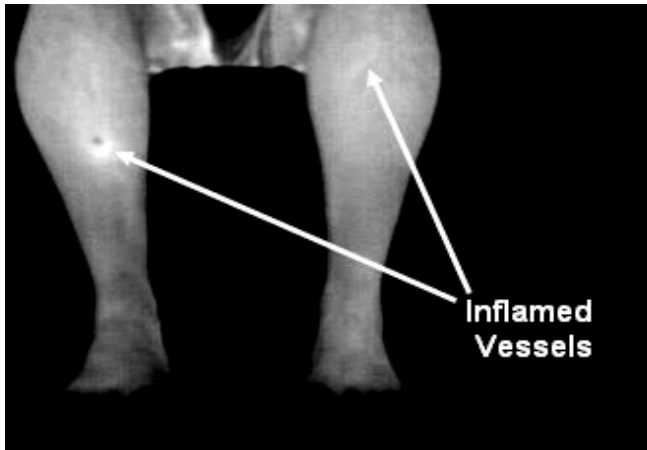


Figure 12a. Before

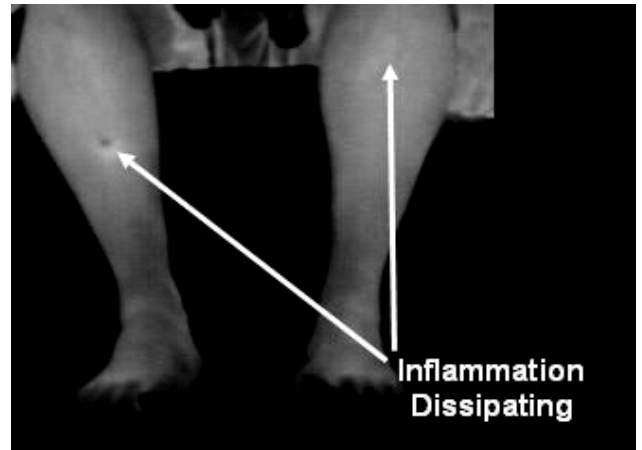


Figure 12b. After

Before	R	L
Post Tibial Pulse Quality	0	1
Pedal Pulse Quality	3	2

Table 6a. Before

After	R	L
Post Tibial Pulse Quality	1	3
Pedal Pulse Quality	3	5

Table 6b. After

In the Thermographic images above, Figures 11a and 12a, a marked inflammation, including inflammation of the blood vessels was shown before the application of the acoustic/magnetic field. In the followup Thermography, Figures 11b and 12b, a marked decrease in inflammation and an increase in perfusion was shown as evidenced by the concurrent improvement in both post tibial and pedal pulse quality shown in Table 6a as compared to Table 6b after the application of the acoustic/magnetic field. A marked bilateral decrease in edema was shown as well.

Subject 7

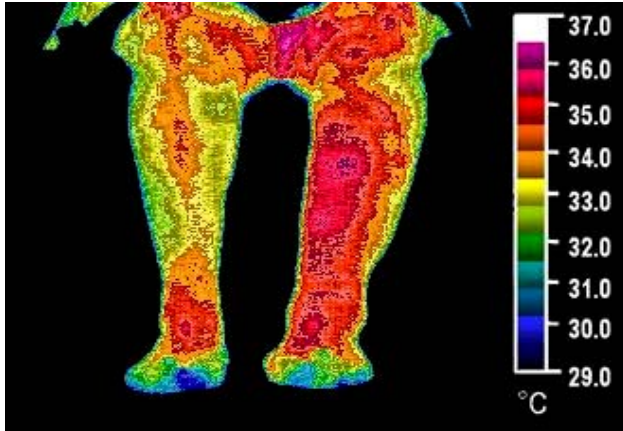


Figure 13a. Before

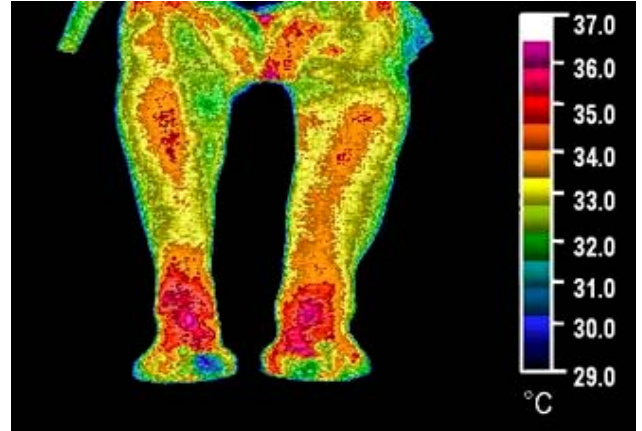


Figure 13b. After

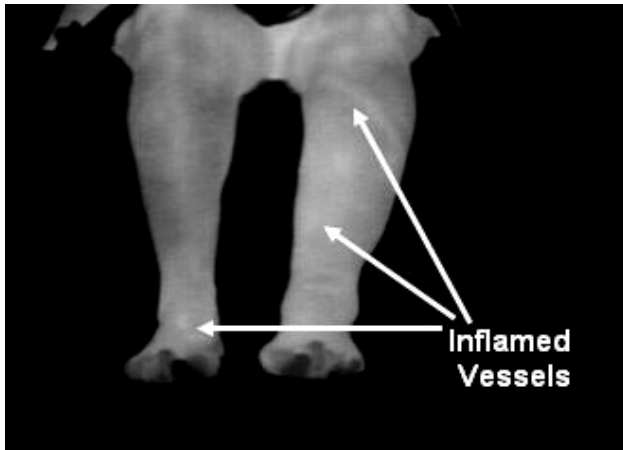


Figure 14a. Before

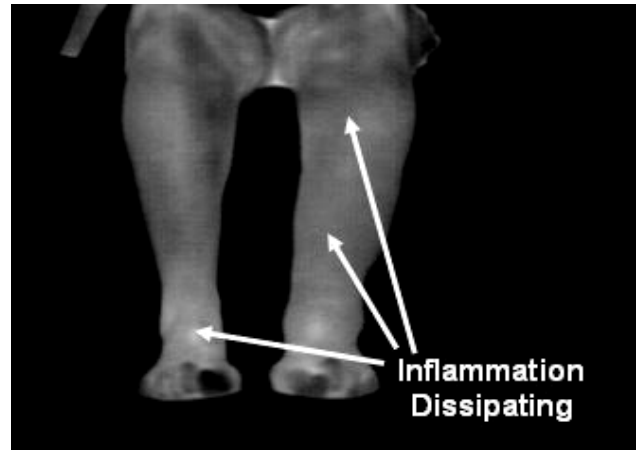


Figure 14b. After

Before	R	L
Post Tibial Pulse Quality	1	0
Pedal Pulse Quality	3	0

Table 7a. Before

After	R	L
Post Tibial Pulse Quality	1	2
Pedal Pulse Quality	4	2

Table 7b. After

In the Thermographic images above, Figures 13a and 14a, a marked inflammation, including inflammation of the blood vessels was shown before the application of the acoustic/magnetic field. In the followup Thermography, Figures 13b and 14b, a marked decrease in inflammation and an increase in perfusion was shown as evidenced by the concurrent improvement in both post tibial and pedal pulse quality shown in Table 7a as compared to Table 7b after the application of the acoustic/magnetic field. A marked decrease in edema, left leg greater than right, was shown as well.

+Subject 8

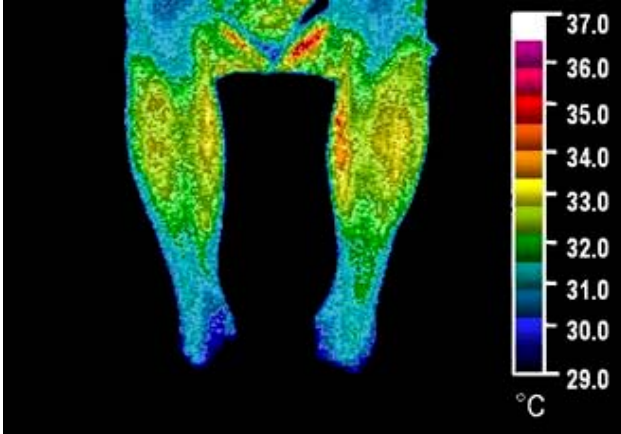


Figure 15a. Before

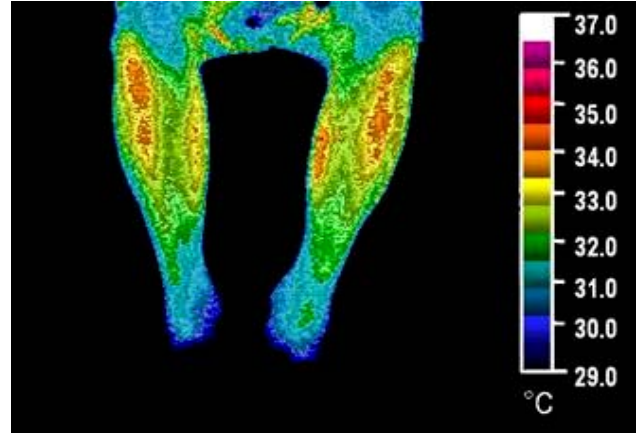


Figure 15b. After

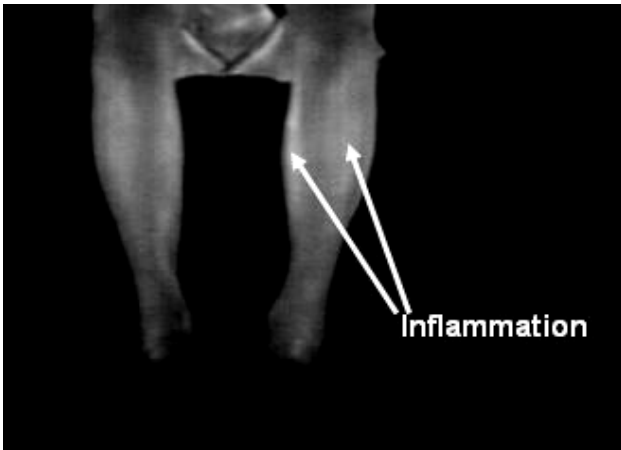


Figure 16a. Before

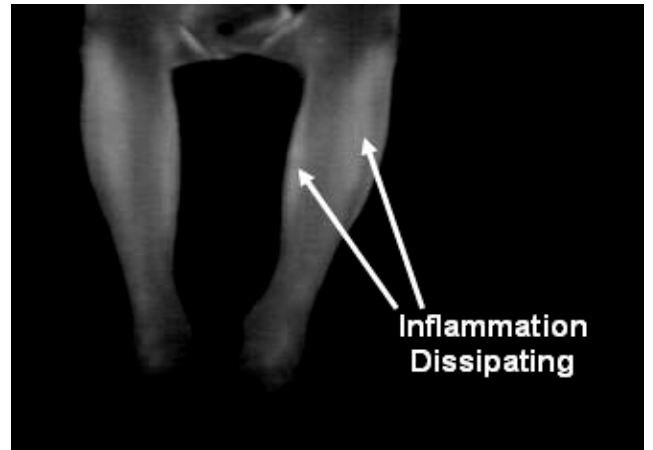


Figure 16b. After

Before	R	L
Post Tibial Pulse Quality	0	1
Pedal Pulse Quality	0	3

Table 8a. Before

After	R	L
Post Tibial Pulse Quality	1	2
Pedal Pulse Quality	3	4

Table 8b. After

In the Thermographic images above, Figures 15a and 16a, a marked inflammation was shown before the application of the acoustic/magnetic field. In the followup Thermography, Figures 15b and 16b, a marked decrease in inflammation and an increase in perfusion was shown as evidenced by the concurrent improvement in both post tibial and pedal pulse quality shown in Table 8a as compared to Table 8b after the application of the acoustic/magnetic field. A marked bilateral decrease in edema was shown as well.

Subject 9

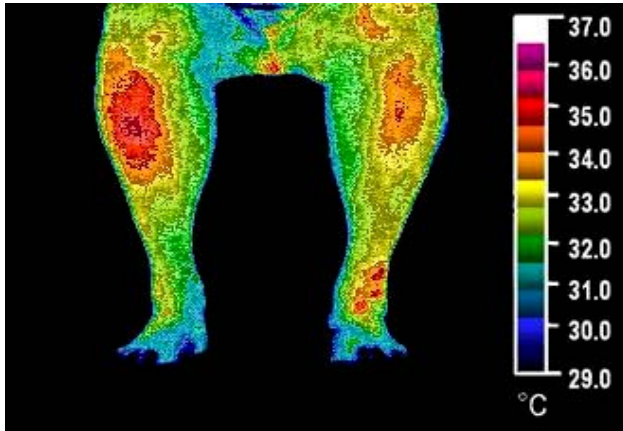


Figure 17a. Before

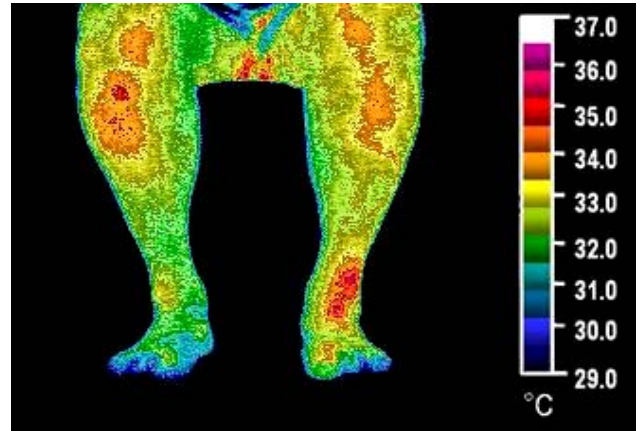


Figure 17b. After

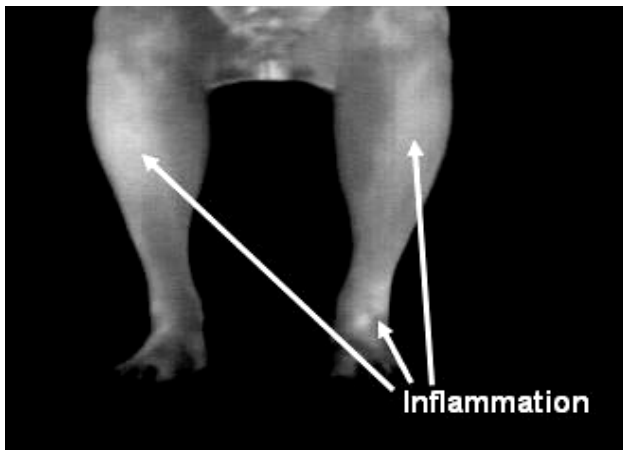


Figure 18a. Before

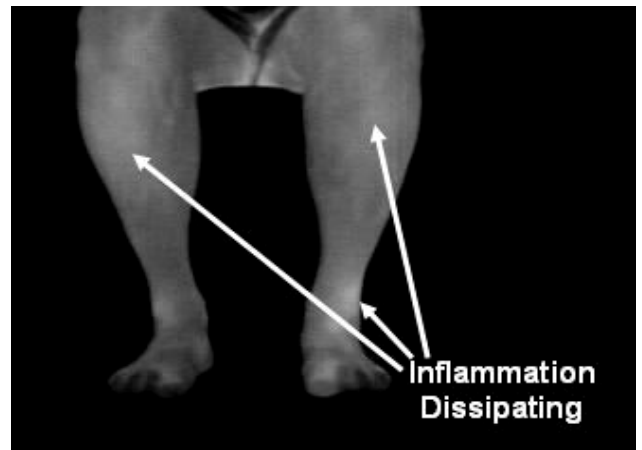


Figure 18b. After

After	R	L
Post Tibial Pulse Quality	1	2
Pedal Pulse Quality	4	5

Table 9a. Before

Before	R	L
Post Tibial Pulse Quality	0	1
Pedal Pulse Quality	3	4

Table 9b. After

In the Thermographic images above, Figures 17a and 18a, a marked inflammation was shown before the application of the acoustic/magnetic field. In the followup Thermography, Figures 17b and 18b, a marked decrease in inflammation and an increase in perfusion was shown as evidenced by the concurrent improvement in both post tibial and pedal pulse quality shown in Table 9a as compared to Table 9b after the application of the acoustic/magnetic field. A marked bilateral decrease in edema was shown as well.

Conclusion

Based on the very positive results of a prior pilot study, that included a control having normal perfusive ability, and a second group with a range of pathological conditions that included PVD, the current study was planned. The results of the initial pilot showed consistently improved perfusion across all Thermographs after application. Improvements in perfusion were shown across the control group as well as the group with pathologies as evidenced by the changes in the followup Thermographs as compared to the baseline Thermographs.²⁰

The significant reduction of inflammation and edema in the cohort with PVD in this current study was a vital intervention in the progression of the disease process as well as a means to halt further tissue destruction that results in the progression of fibrosis that, in turn, causes additional arterial obstruction and ischemia.

The results of this investigation were very positive. Objective improvements in perfusion shown by followup Thermography and pulse assessment, that indicated an increase in arterial blood flow and palpable pulse quality, as compared to baseline Thermography and pulse assessment (baseline pulses were absent or greatly diminished in the entire cohort), in 100% of the group under study. Followup Thermography also showed a significant decrease in inflammation in areas of inflammatory PVD, and a significant decrease in dependent edema as well.

Acknowledgements

We would like to sincerely thank Anne Marie Noyman for her Thermography work as well as the entire staff of the Covenant Health Clinic for their assistance, patience, hospitality and kindness.

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