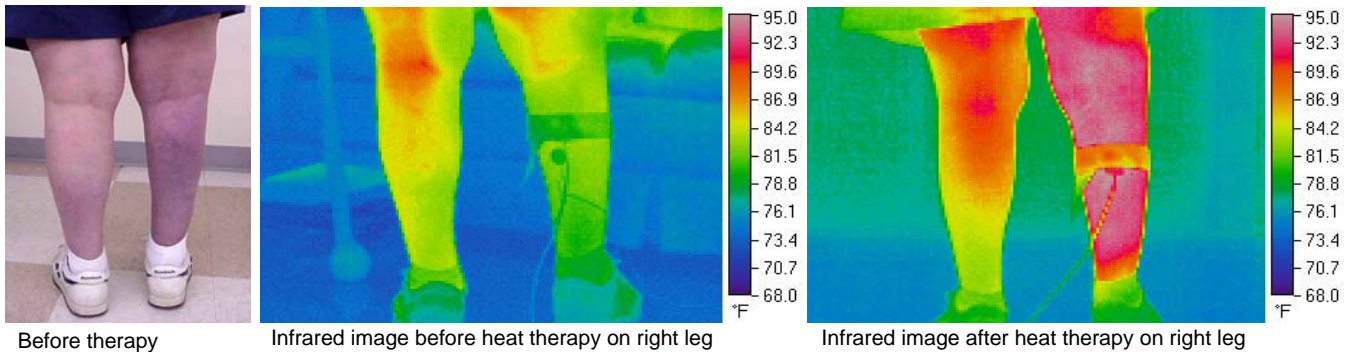


Comparative Effects of Controlled Heat Therapy in Healthy vs. Ailing Leg

Case Study 81806

September 1, 2006



Introduction

The purpose of this test is to compare and measure the effects of heat therapy on the lower legs of a person with one leg ailing and discolored.

Research has shown that effective localized heat therapy begins at a temperature of 104°F (40°C).^{1,2} This temperature is an accepted threshold for muscle relaxation and improved blood flow. It is also a widely accepted fact that water is a very efficient way to warm tissue because of its high specific heat and thermal conductivity.³ Indeed, hydrotherapy (warm water immersion) is a recommended treatment for diabetics to increase circulation.⁴ Yet despite the seemingly simplistic nature of heat therapy, controlled treatment options generally impractical and require a doctor's office visit.⁵ An alternative for at-home treatments can be found in the HTP-1500 water-circulating heat therapy system. Originally sold to hospitals, this pump with pad combination is available by prescription for home use. The HTP-1500 can simulate immersion therapy by enveloping the limb with temperature specific water therapy. The FDA issued a public health advisory recommending systems like this as a safe alternative to electric heating pads.⁶

While the benefits of heat therapy are known and accepted, the measurable effects of such treatments have eluded caregivers and recipients. However, new technologies are making sophisticated monitoring of blood and oxygen in tissue practical and affordable. One such unit is the Masimo RAD-5 Pulse Oximeter. In addition to recording blood oxygen and pulse, this device allows the caregiver to track and trend a person's perfusion index (PI), a relative measurement of pulse strength and an apparent indicator of health.⁷ These tests should demonstrate the effects of heat therapy on similar legs with different circulation, and the ability of the RAD-5 to measure those effects.

Test Method

A HTP-1500 heat therapy pump with medium pad was preheated to 107°F. A reusable transreflectance sensor was taped to the back side of volunteer's right calf. This leg has noticeable skin discoloration. A skin temperature probe was also adhered to the calf. Use of the Masimo RAD5 Pulse Oximeter began 5 minutes prior to the application of heat therapy. At 5 minutes the heat therapy pad was wrapped around the volunteer's lower right leg. Additionally, a probe was inserted in-between layers of the heat therapy pad to record its temperature. Blood oxygenation (SpO₂), pulse and perfusion (PI) data were recorded and later exported to a spreadsheet for review. Skin, pad and room temperatures were recorded manually. The volunteer received 60 minutes of heat therapy. Photos and infrared images of both legs were taken before and after therapy. The same test was repeated on the left leg two days later, with the exception of the sensor being placed on the inside-right of the calf.

Volunteer

Female, age 58. Right leg had 8 major surgeries 1989 to 2005. Right leg is slightly withered with skin discoloration from subcutaneous collection of blood. Volunteer is not known to have diabetes.

Equipment

- 1 HTP-1500 Heat Therapy Pump SN 1120406
- 2 ST-020 Medium Heat Therapy Pad, Lot G1002603D
- 1 Masimo RAD5 Pulse Oximeter, SN 523506
- 1 Reusable Transflectance Sensor, Model TF-I
- 1 Thermistor Thermometer, Model 8402-20
- 4 Disposable Skin Sensor Probes, Lot 6760334
- 1 Computer Laptop
- 1 Micron 7200 Infrared Camera

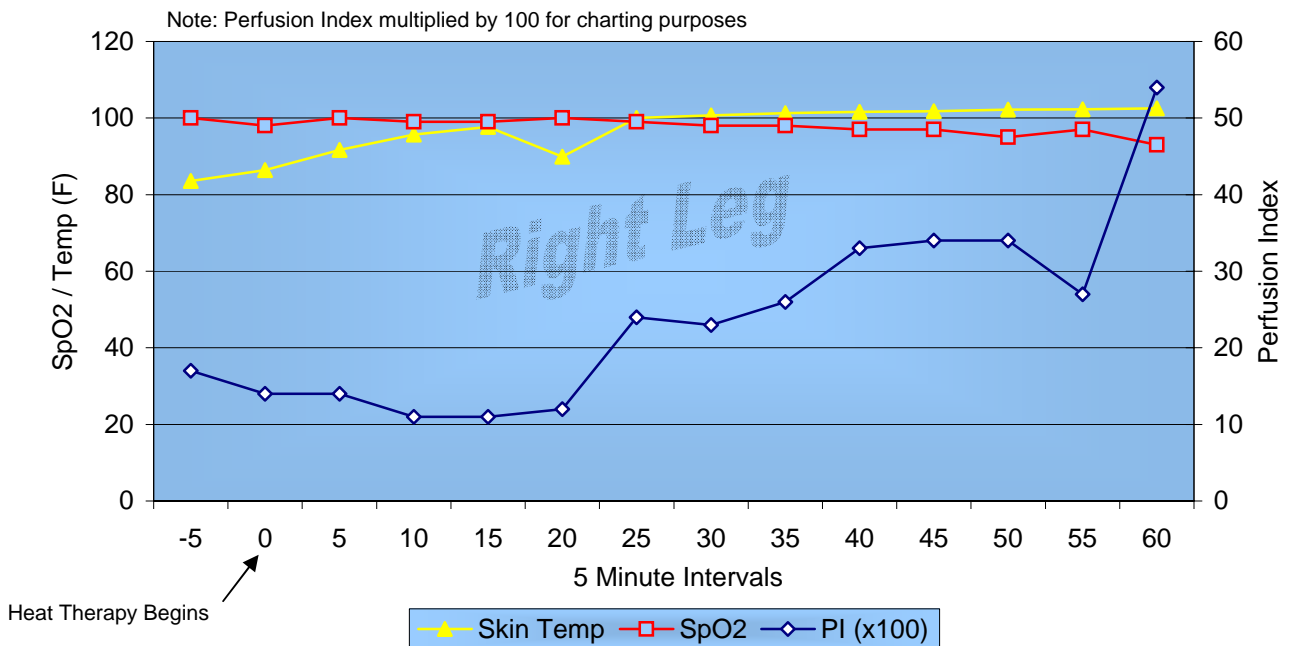
**Data
Right Leg**

Minutes	SpO2	Pulse Rate	Perf. Index	Pad Temp.	Skin Temp.	Room Temp.
-5	100	97	0.17	-	83.6	74
0	98	93	0.14	-	86.4	74
5	100	96	0.14	106.3	91.7	74
10	99	95	0.11	106.5	95.7	74
15	99	96	0.11	106.5	97.7	74
20	100	100	0.12	106.5	89.9	74
25	99	99	0.24	106.5	100.0	75
30	98	95	0.23	106.5	100.7	75
35	98	92	0.26	106.5	101.3	75
40	97	94	0.33	106.5	101.6	75
45	97	98	0.34	106.7	101.8	75
50	95	92	0.34	106.5	102.2	75
55	97	99	0.27	106.5	102.3	75
60	93	90	0.54	106.3	102.5	75

Heat Therapy Begins

**Chart
Right Leg**

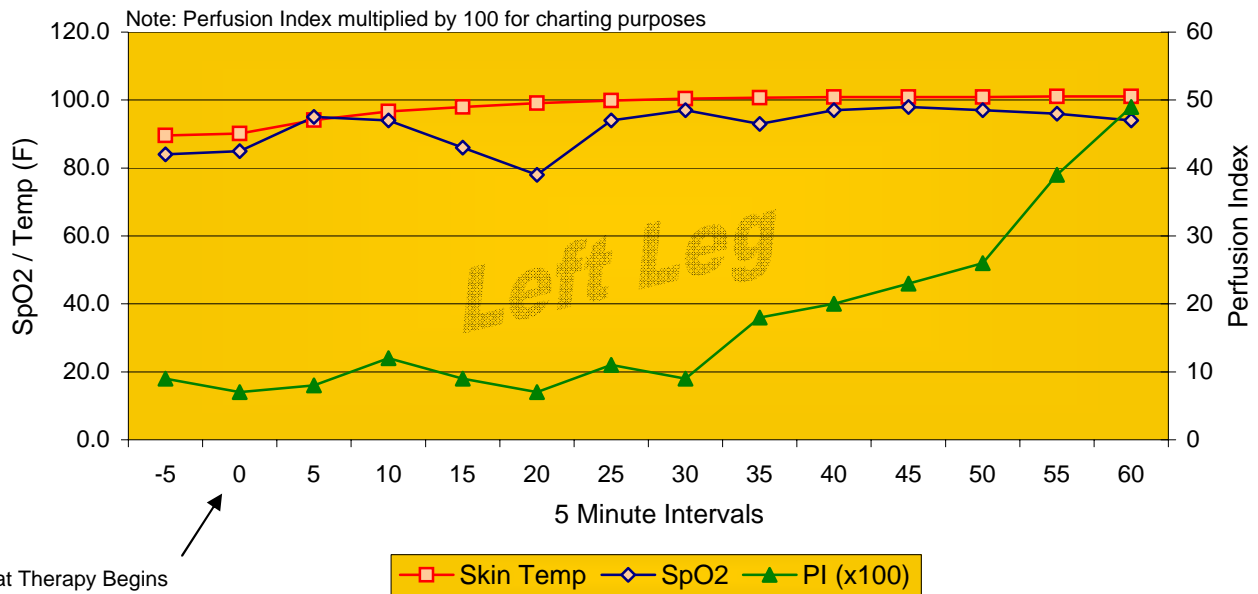
Temperature, SpO2 and Perfusion Index (x100)



Data	Minutes	SpO2	Pulse Rate	Perf. Index	Pad Temp.	Skin Temp.	Room Temp.
Left Leg	-5	84	100	0.09	-	89.6	75
	0	85	95	0.07	-	90.1	75
	5	95	98	0.08	102.5	94.1	75
	10	94	103	0.12	102.9	96.6	75
	15	86	98	0.09	103.1	98.0	75
	20	78	105	0.07	105.0	99.1	75
	25	94	102	0.11	104.1	99.8	75
	30	97	104	0.09	104.7	100.4	75
	35	93	100	0.18	104.9	100.7	75
	40	97	100	0.20	104.7	100.9	75
	45	98	101	0.23	105.0	100.9	75
	50	97	99	0.26	105.0	100.9	75
	55	96	103	0.39	105.5	101.1	75
	60	94	100	0.49	105.2	101.1	75

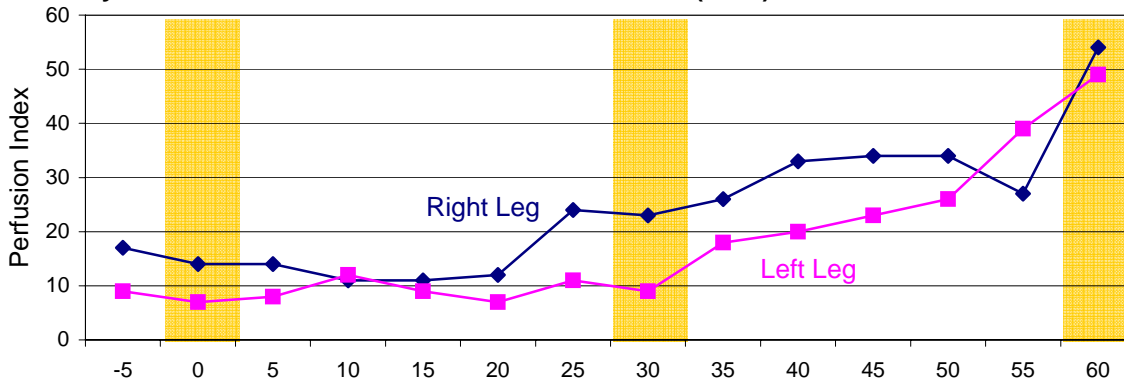
Heat Therapy Begins

Chart Left Leg Temperature, SpO2 and Perfusion Index (x100)



Heat Therapy Begins

Chart Overlay Combined Perfusion Index (x100)



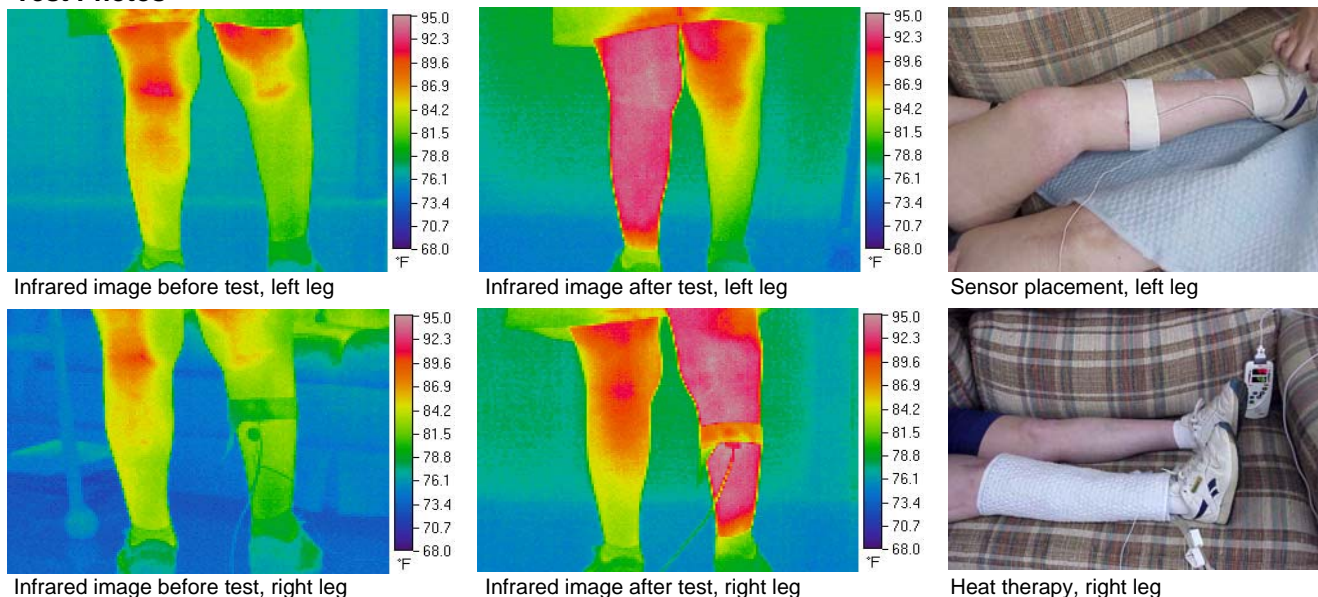
Conclusion

The application of heat therapy produced similar results on both legs with few exceptions. The perfusion index for each leg increased at virtually the same amount despite the fact each leg had a different beginning and ending value. Higher PI values in the right leg are believed caused by the visible subcutaneous collection of blood which the sensor was placed over. As such, the prevailing condition skewed right leg PI values making them appear stronger than left leg PI values. The right leg is clearly not as healthy as the left leg. Therefore, the PI values in the right leg should only be interpreted as relative and not an absolute indicator of health. Still, improvement in PI values was consistent for both legs. Interestingly the oxygenation saturation (SpO2) was also higher in the right leg and did not increase with the application of heat therapy. SpO2 in the left leg did rise steadily in the leg once heat therapy began. It is notable that the pulse rate was lower during right leg testing. No observations were made as to potential reasons for this, other than that the tests were conducted on different days.

Infrared images show strikingly different skin surface temperatures of the legs. Before applying heat therapy the right leg's skin temperature was approximately 81°F, which is 10°F less than average skin temperature for a healthy person.⁸

These tests demonstrate that the HTP-1500 heat therapy system amply increased the amount of arterial blood flow to both legs. These tests also demonstrate that the Masimo RAD-5 Pulse Oximeter with reusable sensor provided consistent measurements despite the obstruction of a subcutaneous collection of blood. However, because of the elevated PI values in the right leg, duplicate tests with the same volunteer are warranted to compare use of alternate pulse oximetry sensors on the toe vs. the calf. Tests are also needed to evaluate the duration of residual effects post heat therapy. And finally, research is needed to further define the significance PI values have as a relative measurement of health.

Test Photos



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