



# Holofiber Study of Thirteen (13) Healthy Subjects

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## **HOLOFIBER STUDY OF THIRTEEN (13) HEALTHY SUBJECTS**

### **OBJECTIVE:**

To evaluate changes in peripheral blood flow in the dorsum of the left arm and the Transmetatarsal region of the foot of a healthy group of thirteen (13) persons when a placebo garment and then Holofiber gloves and stockings are worn. It is expected that subjects when wearing the Holofiber garments will have an increase in local tissue perfusion compared to baseline and control garments. The study outcomes are Transcutaneous Oxygen (T<sub>cp</sub>O<sub>2</sub>) measurements over the course of one hour each for the placebo and the garment trials, with a ten (10) minute equalization of the probes prior to the start of data acquisition with a 30 minute rest period between studies.

### **STUDY DESIGN:**

This will be an evaluation of changes in peripheral perfusion. Subjects will be selected from a healthy population of males and females between the ages of 18 – 50 and will act as their own controls. I plan to enroll thirteen (13) subjects without a history of diabetes or peripheral vascular disease. Subjects will be evaluated by way of transcutaneous oxygen tension measurement for baseline blood flow status over a period of one (1) hour following a ten (10) minute probe equalization period, during this time the subjects will wear a placebo garment, there will be a 30 minute break between the placebo trial and the product trial.

Subjects will have transcutaneous oxygen measurements recorded using Radiometer TCM 30 Modules supplied by Radiometer America, Inc., Ohio, and modified Clarke Electrodes supplied by Radiometer America, Inc., data will be acquired using Perisoft Version 2.10 supplied by Perimed America, Inc. of North Royalton, Ohio. Each subject will wear stockings and gloves made with and without Holofiber.

Measurements will be recorded prior to wearing the product garments and continuously over a one hour period. I will analyze data at ten (10) minute intervals. Following the 30 minute break, recorded measurements will be taken of both the left arm on the dorsum at a point of mid ulna/radius and left foot at the Transmetatarsal region with study subjects wearing Holofiber versus standard fiber gloves and stockings, the latter being used as the placebo for the purposes of the study. *See Fig. 1 below for study design details*

<b><u>Step</u></b>	<b><u>Duration</u></b>
Placebo Equalization	10 minutes
Placebo Study	60 minutes
Rest Period	30 minutes
Product Equalization	10 minutes
Product Study	60 minutes
Totals	170 minutes

*Fig. 1*



## **INCLUSION CRITERIA:**

1. No known family history of Diabetes or Peripheral Vascular Disease
2. Subjects 18 - 50 years old

## **EXCLUSION CRITERIA:**

1. Patient currently being treated by dialysis, or having serum creatinine greater than or equal to 3.0 mg/dl.
2. Patient known to be an active alcohol or substance abuser for the six months prior to the start of the study.

Subjects will also be excluded if any of the following apply:

1. The use of corticosteroids in a dose equivalent to greater than or equal to 10 mg of prednisone per day.
2. Has ever received immunosuppressive agents.
3. Has ever undergone radiation therapy.
4. Has ever received cytotoxic agents.
5. Subject currently receiving antiviral agents.
6. Subject is a female who is breast feeding, pregnant, or attempting to become pregnant.
7. Patient has other conditions considered by the investigator to be sound reasons for disqualification (e.g., acute illness or exacerbation of chronic illness, lack of motivation, and history of poor compliance).
8. Any history of vascular disease including Arterial or Venous insufficiency.
9. Any history heart disease.

## **METHOD:**

The dynamic non-invasive vascular assessment consisted of transcutaneous oxygen pressure (TcPO<sub>2</sub>) measurement. I used the Radiometer TCM30 module and data will be acquired using the Perisoft data acquisition software.

The study was non-invasive, and each subject has given verbal consent to the study after an explanation of the methods was explained. Each subject was requested not to smoke or consume liquid containing caffeine at least three (3) hours pre-study.

Preparation of the subject was standardized to the following, the hair was shaved from the test sites, the dermis was then abraded with a fine abrasive material, the stratum corneum was then removed by the use of light weight adhesive tape, and finally the probe site was wiped with an alcohol preparation swab.



Subjects were then situated in a semi-recumbent position of a Straker gurney, the laboratory was maintained at a constant temperature of 21° C over the duration of the study.

The transcutaneous oxygen electrodes were heated to 45°C and allowed to equilibrate on the skin for ten (10) minutes (until stable values are achieved). The resultant values are measured in mmHg, and is defined as the Partial Pressure or Tension of Oxygen (PpO<sub>2</sub>). Two self-adhesive fixation rings were affixed and the probes attached thereto. A buffer (KCl) solution was to be used at a rate of three (3) drops in each fixation ring, the probe, a modified Clarke Electrode with heating element and thermistor was to be utilized. Each module was to be calibrated to an assumed atmospheric pressure of 159 mmHg, this being 20.9% of the standard atmospheric pressure of 760 mmHg, in doing this each patient had the same baseline atmospheric pressure, thus alleviating any pressure changes due to weather variations during the periods of testing. No humidity control was taken into consideration during this study.

I measured transcutaneous oxygen continuously during the one (1) hour placebo evaluation period and recorded seven (7) values for two (2) minutes at each selected marker at random on the dorsum of the foot and hand. During the product trial, I measured continuously and made seven (7) random selections of the 60 minute data collection period at two (2) minute duration each. At the conclusion of each data collection period two (2) comparisons will be made to show the differences recorded between the placebo and the product as outlined in the attached preliminary results.

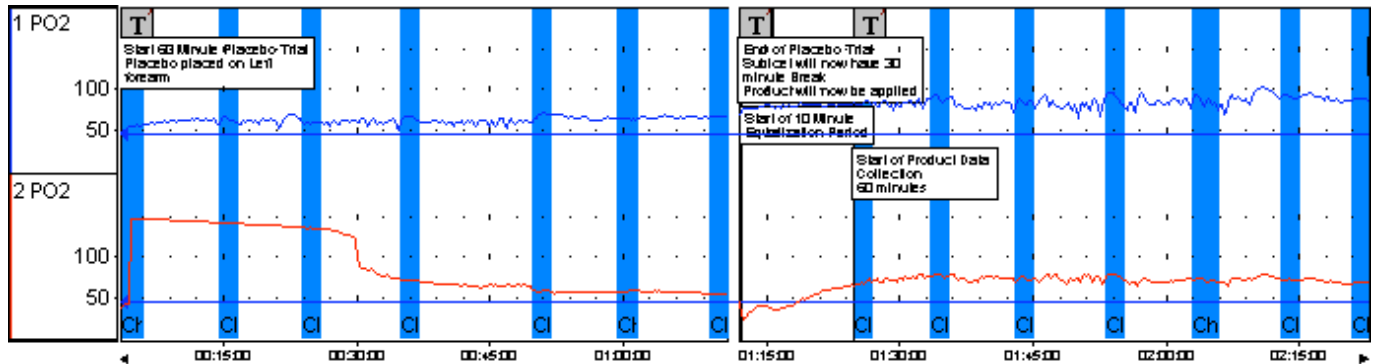


**PRELIMINARY RESULTS:**

**SUBJECT 1**

Comment: Male, 32 years of age  
 Non Smoker  
 Weight: 211 lbs., Height: 5' 7",  
 BP: 137/85

**Percent Change Areas**



**Mean value channel 1 : PO<sub>2</sub>**

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	52.51	61.57	58.50	63.73	67.33	62.70	65.46	82.23	88.60	83.64	90.30	85.14	90.22	87.18	74.22

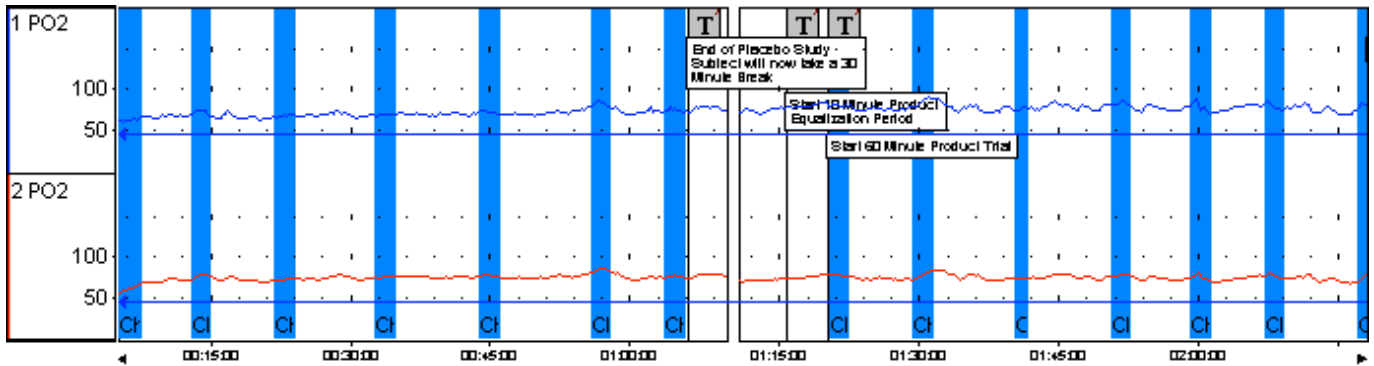
**Mean value channel 2 : PO<sub>2</sub>**

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	105.7	141.3	135.0	70.47	57.42	57.27	53.69	67.90	76.89	72.41	76.23	70.73	70.85	68.34	80.30



**SUBJECT 2**

Comment: Hispanic Male, 23 years of age  
 Non Smoker.  
 Weight: 182 lbs., Height: 5' 7"  
 BP: 132/78



**Mean value channel 1 : PO<sub>2</sub>**

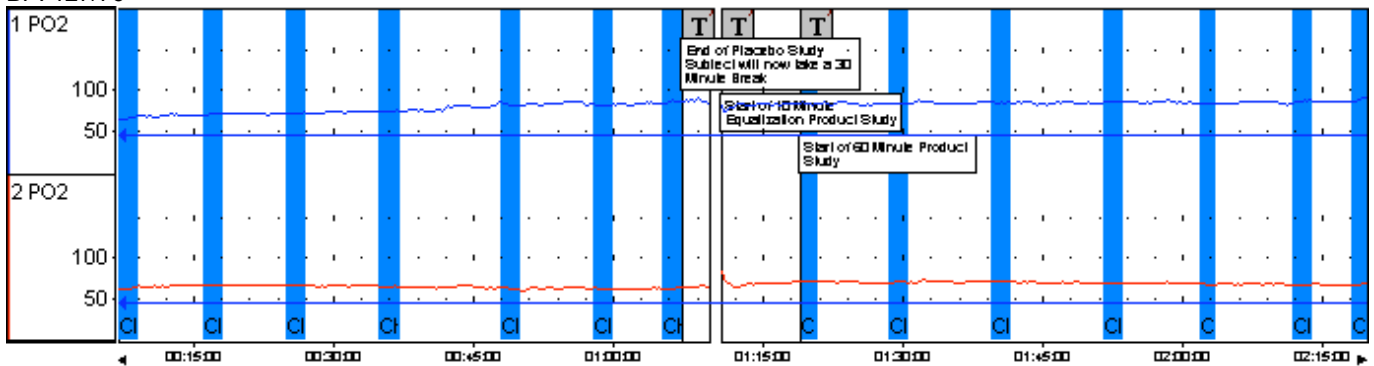
Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	61.46	71.42	66.67	68.44	71.15	81.74	73.58	78.80	84.17	75.46	81.92	78.58	78.44	79.67	75.11

**Mean value channel 2 : PO<sub>2</sub>**

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	60.47	76.78	71.86	74.80	76.66	83.61	75.54	76.81	77.62	72.96	77.11	75.38	76.29	73.47	74.95

**SUBJECT 3**

Comment: White Female, 21 years of age  
 Smoker  
 Weight: 123 lbs., Height: 5' 8"  
 BP: 127/76





**Mean value channel 1 : PO<sub>2</sub>**

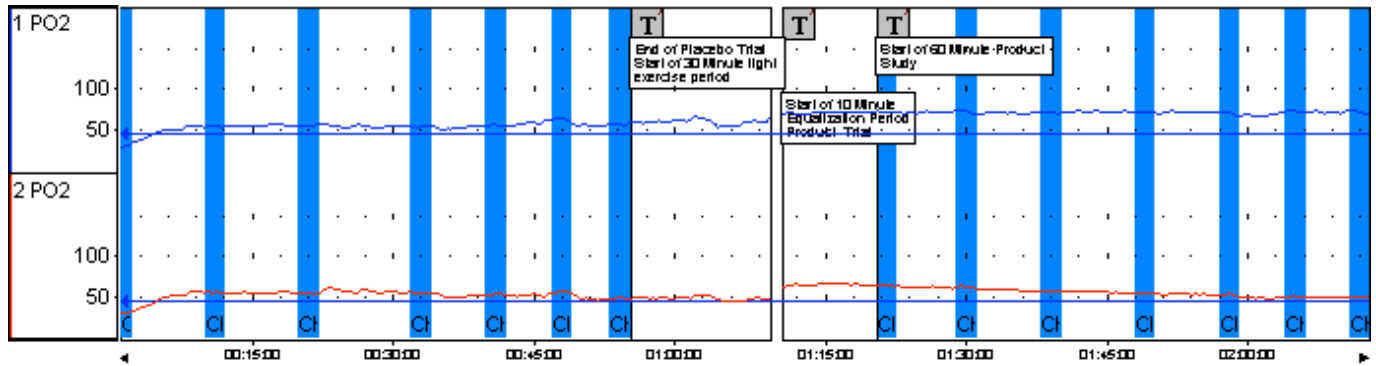
Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	65.22	69.75	71.26	73.49	81.56	81.23	84.99	82.92	83.26	84.25	84.97	82.66	85.97	87.74	79.95

**Mean value channel 2 : PO<sub>2</sub>**

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	61.77	66.09	65.54	63.84	62.03	61.54	62.30	70.40	69.58	71.14	68.56	67.01	65.96	66.41	65.87

**SUBJECT 4**

Comment: Female, 43 years of age  
 Non Smoker  
 Weight: 152 lbs., Height: 5' 6"  
 BP: 118/78



**Mean value channel 1 : PO<sub>2</sub>**

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	29.07	52.60	54.27	53.21	54.55	62.55	56.05	70.97	71.21	70.35	70.57	69.53	71.97	70.78	61.26

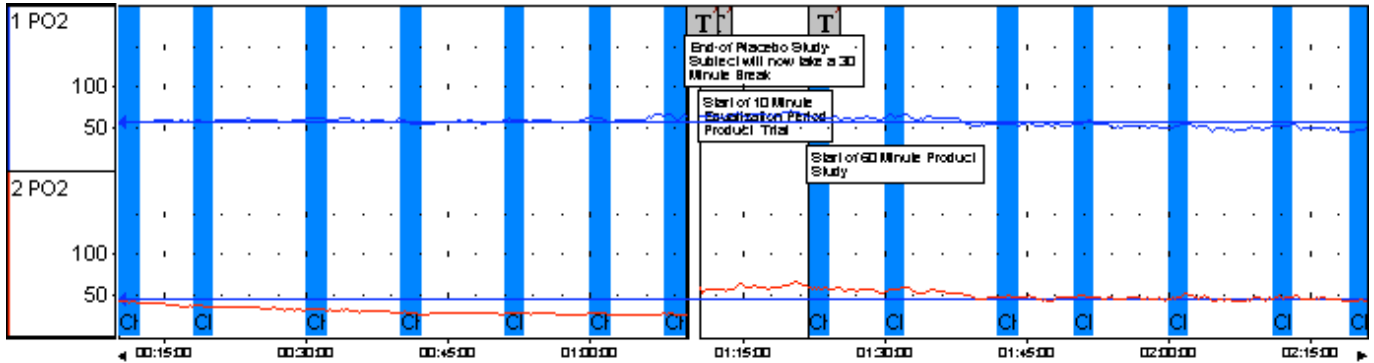
**Mean value channel 2 : PO<sub>2</sub>**

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	29.12	54.92	52.97	54.03	51.68	55.14	47.01	63.00	61.79	56.86	53.35	51.74	49.19	49.34	52.15



**SUBJECT 5**

Comment: White Male, 29 years of age  
 Non Smoker  
 Weight: 270 lbs., Height: 5" 10"  
 BP: 134/76



**Mean value channel 1 : PO<sub>2</sub>**

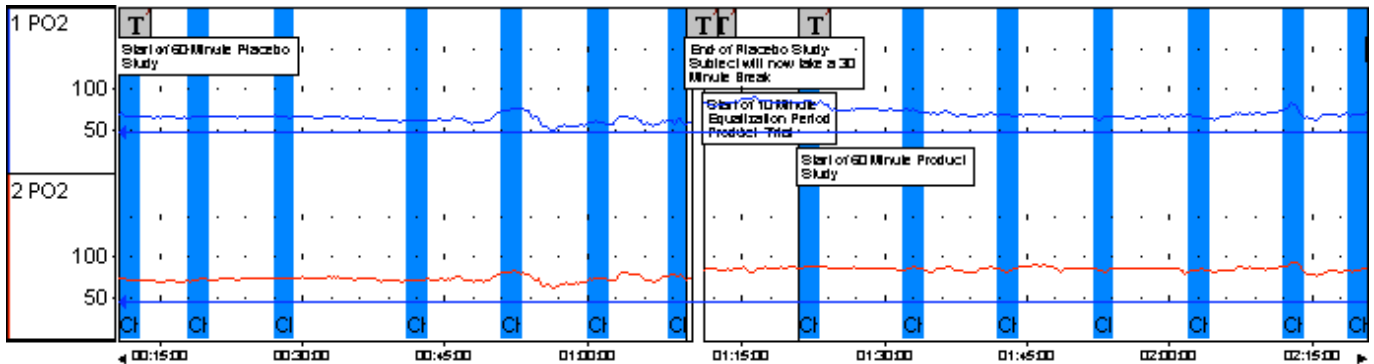
Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	55.80	57.28	60.76	55.87	59.15	60.42	62.79	62.07	63.91	53.51	55.36	51.75	51.31	46.37	56.88

**Mean value channel 2 : PO<sub>2</sub>**

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	40.57	35.29	31.28	26.77	27.10	26.48	24.87	57.15	56.03	47.23	47.26	46.80	46.22	42.43	39.68

**SUBJECT 6**

Comment: White Male, 24 years of age  
 Non Smoker  
 Weight: 225 lbs., Height: 6' 0"  
 BP 148/86







**Mean value channel 1 : PO<sub>2</sub>**

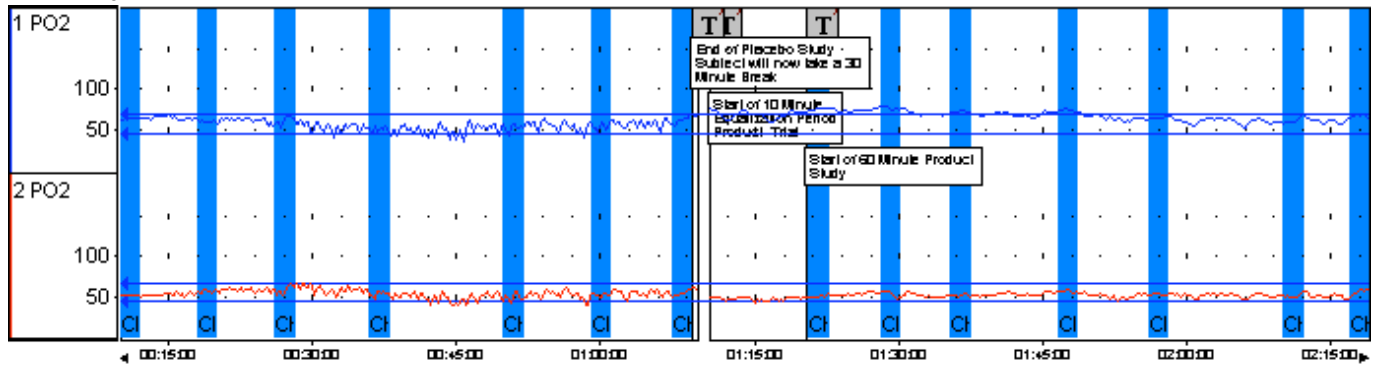
Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	66.95	65.03	65.37	60.88	74.05	58.72	59.32	66.95	65.03	65.37	60.88	74.05	58.72	59.32	67.77

**Mean value channel 2 : PO<sub>2</sub>**

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	71.25	71.06	73.43	71.36	80.91	73.02	75.64	87.55	85.67	83.67	83.11	83.53	90.21	83.32	79.55

**SUBJECT 7**

Comment: White Male, 32 years of age  
 Non Smoker  
 Weight: 220 lbs., Height: 5' 7"  
 BP 122/76



**Mean value channel 1 : PO<sub>2</sub>**

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	62.73	59.33	60.70	49.25	50.91	52.50	61.59	74.45	75.80	71.58	72.62	63.71	60.16	66.32	62.97

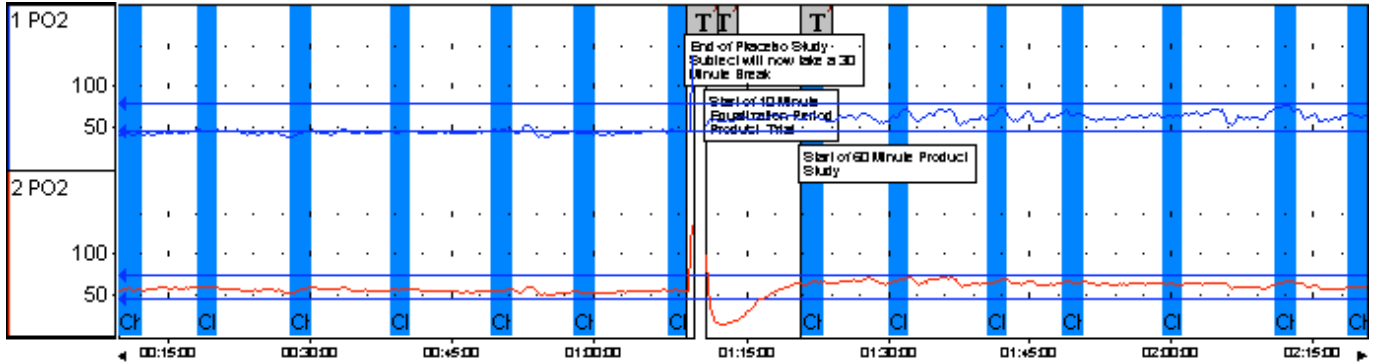
**Mean value channel 2 : PO<sub>2</sub>**

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	51.17	56.60	57.65	53.15	49.21	51.29	54.27	49.84	53.11	51.36	56.49	52.38	50.32	55.98	53.06



**SUBJECT 8**

Comment: White Male, 23 years of age  
 Smoker  
 Weight: 177 lbs., Height: 5' 9"  
 BP



**Mean value channel 1 : PO<sub>2</sub>**

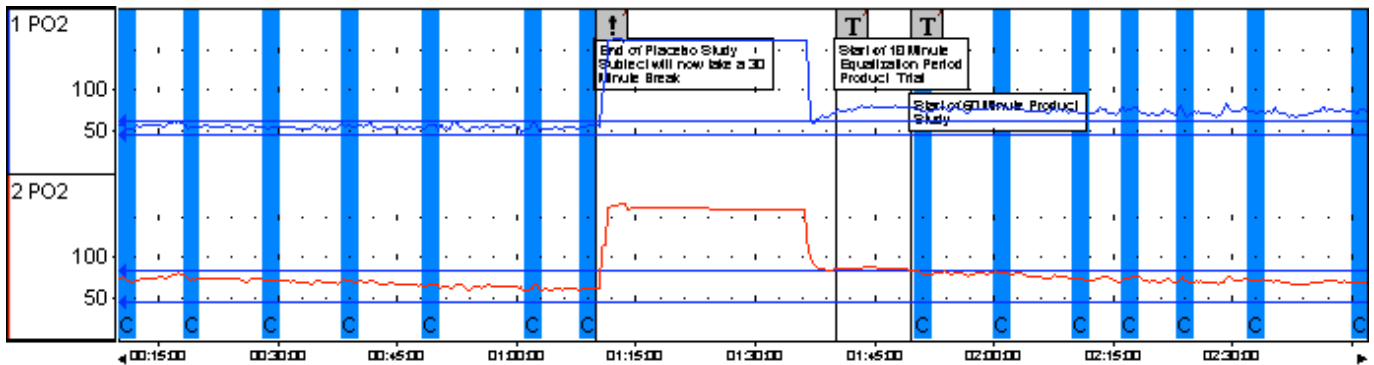
Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	40.21	44.56	41.45	42.86	45.63	41.22	44.78	61.95	64.74	67.84	66.13	62.55	73.45	63.49	54.35

**Mean value channel 2 : PO<sub>2</sub>**

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	55.57	58.23	54.59	55.08	54.58	51.94	54.28	63.86	66.54	65.61	64.85	62.59	64.64	59.00	59.38

**SUBJECT 9**

Comment: Hispanic Male, 22 years of age  
 Non Smoker  
 Weight: 180 lbs., Height: 5' 7"  
 BP 128/72





**Mean value channel 1 : PO<sub>2</sub>**

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	53.83	54.12	52.73	55.17	54.10	54.12	55.23	73.82	78.59	70.96	76.91	72.29	72.51	73.45	64.13

**Mean value channel 2 : PO<sub>2</sub>**

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	71.50	73.64	70.59	69.86	65.00	61.89	60.97	80.17	80.90	72.47	74.01	70.80	70.95	68.63	70.81

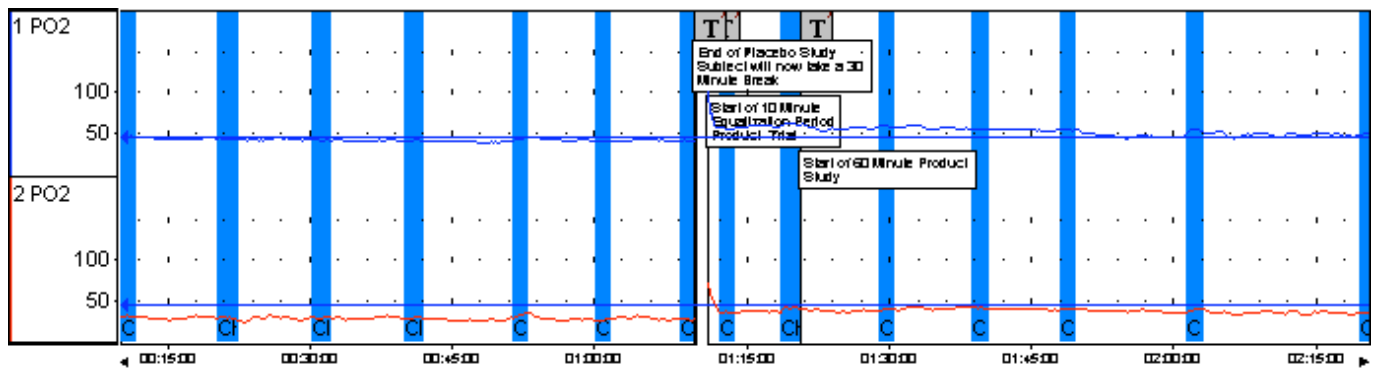
**SUBJECT 10**

Comment: White Male, 45 years of age

Non Smoker

Weight: 157 lbs., Height: 5' 7"

BP 137/82



**Mean value channel 1 : PO<sub>2</sub>**

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	44.68	42.31	40.45	40.07	41.72	38.89	40.02	55.19	59.96	57.12	52.85	53.47	52.87	48.40	47.71

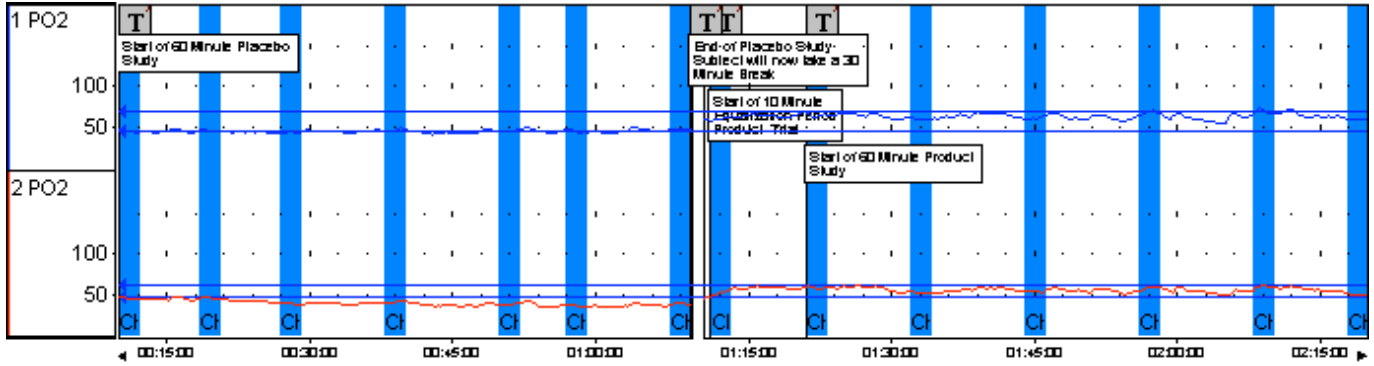
**Mean value channel 2 : PO<sub>2</sub>**

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	29.41	27.81	28.03	27.75	31.32	25.61	25.64	34.21	40.06	38.60	40.44	39.04	37.49	34.06	32.82



**SUBJECT 11**

Comment: White Male, 27 years of age  
 Non Smoker  
 Weight: 195 lbs., Height: 5' 7"  
 BP 132/88



Mean value channel 1 : PO<sub>2</sub>

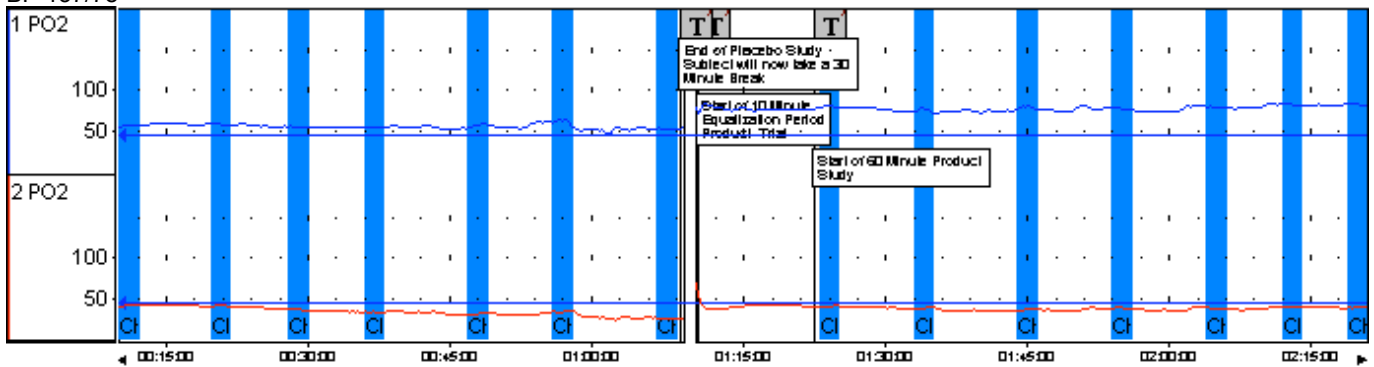
Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	43.72	44.71	42.37	45.60	44.55	43.88	46.93	59.56	63.30	59.14	60.41	66.90	68.77	57.92	53.41

Mean value channel 2 : PO<sub>2</sub>

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	44.46	44.84	37.98	40.22	37.50	35.78	37.93	51.87	57.80	52.06	52.80	57.63	58.72	49.27	47.06

**SUBJECT 12**

Comment: White Female, 44 years of age  
 Non Smoker  
 Weight: 130 lbs., Height: 5' 9"  
 BP 137/78





**Mean value channel 1 : PO<sub>2</sub>**

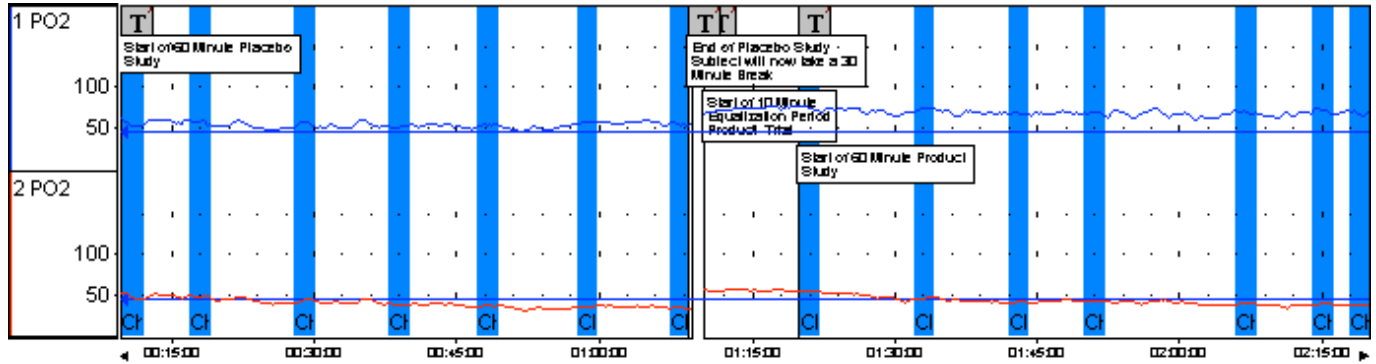
Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	55.37	57.07	54.35	53.62	56.44	61.37	52.02	79.35	74.93	78.38	76.58	78.16	81.70	81.52	67.20

**Mean value channel 2 : PO<sub>2</sub>**

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	41.01	40.34	35.60	32.82	30.32	32.98	25.06	39.95	37.33	35.86	37.84	37.25	39.58	38.25	36.02

**SUBJECT 13**

Comment: White Female, 47 years of age  
 Non Smoker  
 Weight: 130 lbs., Height: 5' 5"  
 BP 118/80



**Mean value channel 1 : PO<sub>2</sub>**

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	53.61	55.76	54.48	49.76	52.53	55.67	53.79	73.16	71.84	66.51	67.10	68.03	70.36	66.89	61.39

**Mean value channel 2 : PO<sub>2</sub>**

Item	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	All areas
Mean value	47.43	47.15	42.76	36.98	35.85	34.87	33.37	53.75	44.93	40.19	41.04	38.94	38.43	36.94	40.90

Subject #	Sex	Age	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area Av PL	Area 8	Area 9	Area 10	Area 11	Area 12	Area 13	Area 14	Area Av PR	% Change PL v PR
1	M	32.75	52.51	61.57	58.50	63.73	67.33	62.70	65.46	<b>61.69</b>	82.23	88.60	83.64	90.30	85.14	90.22	87.18	<b>86.76</b>	40.65%
1			105.72	141.33	135.01	70.47	57.42	57.27	53.69	<b>88.70</b>	67.90	76.89	72.41	76.23	70.73	70.85	68.34	<b>71.91</b>	-18.93%
2	M	23.50	61.46	71.42	66.67	68.44	71.15	81.74	73.58	<b>70.64</b>	78.80	84.17	75.46	81.92	78.58	78.44	79.67	<b>79.58</b>	12.66%
2			60.47	76.78	71.86	74.80	76.66	83.61	75.54	<b>74.25</b>	76.81	77.62	72.96	77.11	75.38	76.29	73.47	<b>75.66</b>	1.91%
3	F	20.85	65.22	69.75	71.26	73.49	81.56	81.23	84.99	<b>75.36</b>	82.92	83.26	84.25	84.97	82.66	85.97	87.74	<b>84.54</b>	12.18%
3			61.77	66.09	65.54	63.84	62.03	61.54	62.3	<b>63.30</b>	70.4	69.58	71.14	68.56	67.01	65.96	66.41	<b>68.44</b>	8.11%
4	F	43.72	29.07	52.6	54.27	53.21	54.55	62.55	56.05	<b>51.76</b>	70.97	71.21	70.35	70.57	69.53	71.97	70.78	<b>70.77</b>	36.73%
4			29.12	54.92	52.97	54.03	51.68	55.14	47.01	<b>49.27</b>	63	61.79	56.86	53.35	51.74	49.19	49.34	<b>55.04</b>	11.71%
5	M	29.25	55.8	57.28	60.76	55.87	59.15	60.42	62.79	<b>58.87</b>	62.07	63.91	53.51	55.36	51.75	51.31	46.37	<b>54.90</b>	-6.74%
5			40.57	35.29	31.28	26.77	27.1	26.48	24.87	<b>30.34</b>	57.15	56.03	47.23	47.26	46.8	46.22	42.43	<b>49.02</b>	61.57%
6	M	24.37	66.95	65.03	65.37	60.88	74.05	58.72	59.32	<b>64.33</b>	66.95	65.03	65.37	60.88	74.05	58.72	59.32	<b>64.33</b>	0.00%
6			71.25	71.06	73.43	71.36	80.91	73.02	75.64	<b>73.81</b>	87.55	85.67	83.67	83.11	83.53	90.21	83.32	<b>85.29</b>	15.56%
7	M	32.65	62.73	59.33	60.7	49.25	50.91	52.5	61.59	<b>56.72</b>	74.45	75.8	71.58	72.62	63.71	60.16	66.32	<b>69.23</b>	22.07%
7			51.17	56.6	57.65	53.15	49.21	51.29	54.27	<b>53.33</b>	49.84	53.11	51.36	56.49	52.38	50.32	55.98	<b>52.78</b>	-1.03%
8	M	23.95	40.21	44.56	41.45	42.86	45.63	41.22	44.78	<b>42.96</b>	61.95	64.74	67.84	66.13	62.55	73.45	63.49	<b>65.74</b>	53.02%
8			55.57	58.23	54.59	55.08	54.58	51.94	54.28	<b>54.90</b>	63.86	66.54	65.61	64.85	62.59	64.64	59.00	<b>63.87</b>	16.35%
9	M	22.70	53.83	54.12	52.73	55.17	54.1	54.12	55.23	<b>54.19</b>	73.82	78.59	70.96	76.91	72.29	72.51	73.45	<b>74.08</b>	36.71%
9			71.5	73.64	70.59	69.86	65	61.89	60.97	<b>67.64</b>	80.17	80.9	72.47	74.01	70.8	70.95	68.63	<b>73.99</b>	9.39%
10	M	44.30	44.68	42.31	40.45	40.07	41.72	38.89	40.02	<b>41.16</b>	55.19	59.96	57.12	52.85	53.47	52.87	48.40	<b>54.27</b>	31.83%
10			29.41	27.81	28.03	27.75	31.32	25.61	25.64	<b>27.94</b>	34.21	40.06	38.60	40.44	39.04	37.49	34.06	<b>37.70</b>	34.94%
11	M	27.90	43.72	44.71	42.37	45.6	44.55	43.88	46.93	<b>44.54</b>	59.56	63.30	59.14	60.41	66.90	68.77	57.92	<b>62.29</b>	39.85%
11			44.46	44.84	37.98	40.22	37.5	35.78	37.93	<b>39.82</b>	51.87	57.80	52.06	52.80	57.63	58.72	49.27	<b>54.31</b>	36.40%
12	F	44.75	55.37	57.07	54.35	53.62	56.44	61.37	52.02	<b>55.75</b>	79.35	74.93	78.38	76.58	78.16	81.70	81.52	<b>78.66</b>	41.10%
12			41.01	40.34	35.60	32.82	30.32	32.98	25.06	<b>34.02</b>	39.95	37.33	35.86	37.84	37.25	39.58	38.25	<b>38.01</b>	11.73%
13	F	46.90	53.61	55.76	54.48	49.76	52.53	55.67	53.79	<b>53.66</b>	73.16	71.84	66.51	67.10	68.03	70.36	66.89	<b>69.13</b>	28.83%
13			47.43	47.15	42.76	36.98	35.85	34.87	33.37	<b>39.77</b>	53.75	44.93	40.19	41.04	38.94	38.43	36.94	<b>42.03</b>	5.68%
		32.12																	
			52.70	56.58	55.64	54.77	57.97	58.08	58.20	<b>56.28</b>	70.88	72.72	69.55	70.51	69.76	70.50	68.39	<b>70.33</b>	24.97%
			54.57	61.08	58.25	52.09	50.74	50.11	48.51	<b>53.62</b>	61.27	62.17	58.49	59.47	57.99	58.37	55.80	<b>59.08</b>	10.18%

Areas 1 -3 = Placebo (PL)  
Areas 4 - 10 = Product (PR)  
Male 9  
Female = 4



## CONCLUSIONS:

All the data that these conclusions are drawn from is contained within the information table on page 13 of this document.

Thirteen (13) subjects were chosen at random and tested in accordance with the protocol within the study design, the breakdown of the subjects was:

Female	N = 4
Male	N = 9

With an age range of 20.85 years to 46.75 years (mean 32.12 years).

Data designated in areas 1 – 7 is the Placebo trial and those data within areas 8 – 14 is the Product trial.

In looking at the collective data it will be noted that with the exception of three (3) subjects, Nos: 1, 5, and 7 there was a substantial increase in oxygen perfusion when using the Holofiber product. These increases in the Placebo versus Product vary in range in the mid radial ulna region of the dorsum, designated channel 1, from 0.00% to 53.02% with a mean of 29.97%, these figures exclude the one (1) subject that showed a negative increase in perfusion levels in this region. In channel 2, the Transmetatarsal region of the foot, increases ranged from 1.91 – 61.57% with the mean being 10.18%, these numbers exclude those subjects that showed a diminished perfusion in this region.

In the case of subjects 1, 5, and 7, it will be noted that in the case of subject 1 there was a decrease in the Transmetatarsal region of 18.93% and in subject 5, there was a decrease of 6.74% in the mid radial ulna region of the dorsum, and in subject 7 a decrease of 1.03% was observed in the metatarsal region of the foot. This discrepancy cannot be explained without further medical investigation which is outside the scope of this study.

Increased oxygen perfusion has been shown to aid in the increase of energy. Energy produced at the cellular level will accelerate muscle tissue recovery from exercise, which is known to induce lactic acid increases, rebuild strength in muscles damaged by exercise, and also reduce the incidence of cramping, edema, and muscle fatigue post strenuous exercise in athletic conditioning.

In conclusion, it is the opinion of this researcher, based on this study, that Holofiber does, in fact, increase oxygen perfusion levels within by 10% to 24% in a healthy non-compromised population.

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Graham M. McClue, Ph.D.

Date