Effect of Shirt with 42% Celliant Fiber on $TCPO_2$ Levels and Grip Strength in Healthy Subjects

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MATERIAL:

Celliant™ technology is a patented process for adding micron sized optically active quartz, silicon oxide and titanium oxide particles to polymer fibers. The resulting Celliant™ yarns are believed to have unique effects on the electromagnetic energy environment of the skin in the visible and near infrared portion of the spectrum leading to increased blood flow and oxygen levels.

OBJECTIVE(S):

This study is designed to assess the effect of a shirt with 42% Celliant™ fiber on $TCPO_2$ levels and grip strength. The two main objectives are: 1) to evaluate changes in peripheral blood flow in healthy subjects when a placebo garment and then a shirt with 42% Celliant fiber is worn; and 2) to assess the impact of wearing a shirt with 42% Celliant™ fiber on the dominate wrist strength as measured by a dynamometer. The two main hypotheses to be tested are: 1) Compared to placebo shirts, subjects wearing the a shirt with Celliant™ fiber experience an increase in local tissue perfusion compared to baseline and control garments; and 2) Compared to placebo shirts, subjects wearing a shirt with Celliant™ fiber experience an increase in grip strength as measured by a dynamometer. It is expected that: 1) Subjects that wear the Celliant™ garments will have an increase in local tissue perfusion compared to baseline and control garments; and that 2) Subjects that wear the Celliant™ garments will have an increase in dominant arm wrist strength compared to control garments. The study outcomes are: 1) Transcutaneous Oxygen ($TCPO_2$) measurements over the course of ninety (90) minutes each for the placebo and the garment trials, with a ten (10) minute equalization of the probes prior to the start of data acquisition and with a fifteen (15) minute interval rest period between studies; and 2) Grip strength measurements taken at two (2) intervals, one (1) each following the ninety (90) minute placebo period and the ninety (90) minute Celliant™ period as measured by a dynamometer in lbs. per square inch.

RESEARCH DESIGN:

This will be an evaluation of changes in peripheral perfusion and an evaluation in changes of grip strength. Subjects will be selected from a healthy population of males and females between the ages of 18–60 and will act as their own controls. Approximately 20 subjects total will be enrolled. Subjects will be evaluated by way of transcutaneous oxygen tension measurement ($TCPO_2$) for baseline blood flow status. A placebo garment will be worn over a period of ninety (90) minutes following a ten (10) minute probe equalization period; there will be a fifteen (15) minute break between the placebo trial and the product trial. Subsequently, the Celliant™ garment will be worn over a period of ninety (90) minutes following a ten (10) minute probe equalization period.

Measurements will be recorded prior to wearing the product garments and continuously over a ninety (90) minute period. Data will be recorded at two (2) minute intervals. Recorded measurements will be taken from the sternum. (For the tests to be conducted by Dr. Gordon, there will be two locations: 1) the bicep of the dominant arm; and 2) the sternum.) The subjects will wear Celliant™ versus a standard garment, the latter being used as the placebo for the purposes of the study.

Grip strength will be measured at two (2) intervals. Once, at the conclusion of the ninety (90) minute placebo period and a second time, at the conclusion of the ninety (90) minute Celliant™ period.

See Fig. 1 below for study design details.

PROCEDURE	DURATION
Vital Measurements	N/A
Grip Strength Practice	N/A
Placebo Equalization	10 minutes
Placebo Study	90 minutes
Vital Measurements	N/A
Grip Strength	N/A
Rest Period	15 minutes
Product Equalization	10 minutes
Product Study	90 minutes
Vital Measurements	N/A
Grip Strength	N/A
Total	215 minutes

Fig. 1

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 a golf shirt made with and without Celliant™.

Furthermore, subjects will have grip strength tested by The Baseline Hydraulic Hand Dynamometer manufactured by Fabrication Enterprises Incorporated.

INCLUSION CRITERIA:

1. Healthy Subjects
2. Subjects 18 – 60 years old

EXCLUSION CRITERIA:

1. Patients that are known to be active smokers for the six months prior to the start of the study.
2. Patients known to be an active alcohol or substance abuser for the six months prior to the start of the study.
3. Patients that are known to have consumed caffeine within 3 hours prior to the test.

METHODOLOGY:

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 seated position on a comfortable chair. The room temperature was maintained at a constant temperature over the duration of the study. Blood pressure, heart rate and body temperature were recorded at three intervals: before the test was administered, after the ninety (90) minute placebo garment period, and finally after the ninety (90) minute Celliant™ garment period.

The transcutaneous oxygen electrodes were heated to 45°C and allowed to equilibrate on the skin for ten (10) minutes (until stable values were achieved). The resultant values were measured in mmHg and defined as the Partial Pressure or Tension of Oxygen (PpO_2).

Two self-adhesive fixation rings were affixed and the probes attached thereto. A buffer (KCl) solution was used at a rate of three (3) drops in each fixation ring; the probe, a modified Clarke Electrode with heating element and thermostat was utilized. Each module was calibrated to an assumed atmospheric pressure of 159 mmHg, 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.

Measurements of transcutaneous oxygen were taken continuously during the ninety (90) minute placebo evaluation period and recorded one (1) value every two (2) minutes. (For the Dr. Gordon protocol, two (2) values for five (5) minutes for each selected period). Blood pressure, heart rate and body temperature were recorded. During the product trial, measurements were taken continuously during the ninety (90) minute and recorded one (1) value every two (2) minutes. (For the Dr. Gordon protocol, two (2) values for five (5) minutes for each selected period). Again, blood pressure, heart rate and body temperature were recorded. At the conclusion of each data collection period, comparisons will be made to show the differences recorded between the placebo and the product.

To record and measure the grip strength of the subjects, the following protocol was followed:

The Baseline Hydraulic Hand Dynamometer, manufactured by Fabrication Enterprises Incorporated, was used. For each test in grip strength, the subject was seated with shoulder adducted and neutrally rotated, elbow flexed at 90°, forearm in neutral position, and wrist between 0° and 30° dorsiflexion and between 0° and 15° ulnar deviation. The dominant arm was tested, and the following was performed:

1) During the intake process, the subject was asked to squeeze the dynamometer initially at less than full strength simply to have the benefit of the experience of holding and using the device.
2) The first measurement was taken following the ninety (90) minute period after the placebo garment was worn. (This serves as the baseline or control measurement).
3) The second measurement was taken following the ninety (90) minute period after the Celliant™ garment was worn. (This serves as the measurement demonstrating the effect of the Celliant™ garment).

FINDINGS:

In two previous clinical studies, Celliant™ garments have been shown to significantly increase tissue oxygenation.

CLINICAL SIGNIFICANCE:

If the study finds that 1) subjects that wear the Celliant™ garments have an increase in local tissue perfusion compared to placebo garments; and/or that 2) subjects that wear the Celliant™ garments have an increase in dominant arm wrist strength compared to control garments, it will further support and validate the efficacy of this type of fabric for increasing tissue oxygenation and/or increasing muscle strength.

ANALYSIS OF PHYSIOLOGIC VARIABLES AND TRANSCUTANEOUS OXYGEN LEVELS WITH STANDARD PET SHIRTS VERSUS CELLIANT® SHIRTS

Presented here are data and statistical analyses of the results from a recent study comparing the physiological effects of wearing shirts constructed from standard PET fabric versus Celliant® optically modified fibers. 24 healthy volunteer subjects wore standard PET shirts for 90 minutes indoors in a constant temperature and indoor light environment. During the measurements subjects were asked to rest quietly in a chair and had refrained from tobacco and caffeine for at least one hour before baseline measurements. In all but one case, the standard PET garment was worn first, and in all cases measurements were carried out over 90 minutes. Following a short break, repeat measurements were performed with the Celliant® garment. Temperature of the abdominal wall skin was determined with a taped on thermistor. Blood pressure and heart rate were determined with standard clinical equipment. Grip strength was determined with a hand dynamometer, with only a single trial at 90 minutes performed to minimize the effects of repeated trials. Transcutaneous oxygen levels ($tcpO_2$) were determined with standard Clarke electrodes calibrated to room air oxygen with skin heated to 44˚C. For most subjects only one electrode, placed on the mid anterior abdominal skin was employed, but in 7 cases three probes [two abdominal, one shoulder] were employed.

TABLE 1. PHYSIOLOGIC VARIABLES

	Systolic BP mmHg		Diastolic BP mmHg		Mean BP mmHg	
	Placebo	Celliant	Placebo	Celliant	Placebo	Celliant
N	24	24	24	24	24	24
Mean	109.38	113.71	70.96	71.38	83.76	85.49
Std. Dev	15.74	14.00	9.05	10.58	10.64	11.39
p Value	0.0198		0.7177		0.1207	

	Pulse Rate		Temperature ˚F		Grip Strength	
	Placebo	Celliant	Placebo	Celliant	Placebo	Celliant
N	24	24	24	24	24	24
Mean	65.67	66.08	92.63	92.75	95.92	105.29
Std. Dev	10.17	10.85	1.95	2.21	26.36	23.82
p Value	0.8127		0.6893		0.0002	

Table 1 shows the results obtained after 90 minutes after donning the garment for all the physiologic variables measured except $tcpO_2$. Statistical comparisons were performed using paired t tests. A modest increase in systolic blood pressure was associated with wearing the Celliant® shirts, averaging 4.3 mm Hg that was statistically significant. However, mean blood pressure [calculated as diastolic + (systolic-diastolic)/3] did not show a similarly statistically significant increment associated with wearing the Celliant® garment. Moreover, the differences in diastolic blood pressure, skin temperature, and pulse were not statistically significant. Additionally, grip strength measurements were statistically significant

and showed an approximate 12% increase associated with the Celliant® shirt (based on the average increase measured per subject).

TABLE 2. AGGREGATE $TCP0_2$ DATA

	Transcutaneous pO_2 mmHg					
	30 minutes		60 minutes		90 minutes	
	Placebo	**Celliant**	**Placebo**	**Celliant**	**Placebo**	**Celliant**
N	38	38	38	38	38	38
Mean	75.4	79.63	74.81	79.52	76.08	81.62
Std. Dev	19.37	17.22	19.52	19.53	20.05	20.27
p Value	0.0417		0.0196		0.0029	

Table 2 shows the overall results for $tcpO_2$ when data for all probes are combined with the 30, 60, and 90 minutes measurements depicted. Again, comparisons were made using paired t tests. There was a statistically significant increase in mean tcpO2 levels associated with wearing the Celliant® shirts observed at all three time points, with the greatest increase, at 90 minutes, reflecting an approximate 7% overall average increase in skin oxygen levels.

TABLE 3. COMPARISON OF ABDOMINAL AND SHOULDER SKIN $TCPO_2$

	Transcutaneous pO_2 mm Hg					
	30 minutes		60 minutes		90 minutes	
	placebo	**Celliant**	**placebo**	**Celliant**	**Placebo**	**Celliant**
			Shoulder			
N	7	7	7	7	7	7
Mean	46.29	60.29	44.14	56.57	45.14	57.86
Std. Dev	11.73	14.37	14.69	18.93	17.43	19.93
p Value	0.0168		0.0393		0.0173	
			Abdominal wall			
N	7	7	7	7	7	7
Mean	70.43	76.57	69.00	74.86	70.71	76.00
Std. Dev	9.88	7.14	8.93	9.58	8.26	10.10
p Value	0.1087		0.1943		0.1406	

Table 3 shows the average $tcpO_2$ measurements recorded in seven subjects where simultaneous recordings of shoulder and abdominal wall skin were performed. Of note, the differences between placebo and Celliant® shirts were statistically significant based on paired t tests, which is remarkable given the small

number of subjects studied in this manner. The abdominal wall skin measurements similarly showed an increase in oxygen levels.

Conclusions: The data shows a minor increase in systolic blood pressure associated with wearing the Celliant® shirts that is too small in magnitude to likely represent a significant health hazard. The increase in grip strength observed was noteworthy and significant, but further study is needed to evaluate this effect in more detail. A study is planned for the near future to measure the effect in more detail, with the plan to vary the sequence of which garment (placebo or Celliant®) is worn first. The increases in $tcpO_2$ levels associated with the Celliant® shirt corroborates earlier findings performed in the limbs that oxygen levels increase when socks or gloves fabricated from Celliant® fibers are worn. Given that, in both trials, the transcutaneous oxygen probes were heated to 44°C and skin temperature levels did not significantly vary between the two garments, it is unlikely that the effect observed is due to increases in skin temperature causing secondary effects on skin blood flow.

In summary, the results of this study strongly suggest that Celliant® fibers have a positive effect on blood flow, unlikely related to skin temperature effects. The data also indicates that strength may be enhanced by wearing Celliant® garments. The vital sign data indicates that the risks of harmful hemodynamic effects are very low. Although the mechanism underlying these results remains unknown, the results are promising, and further study is warranted to characterize the unique effects associated with Celliant® fibers.

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