Summary of Results for the
Study HC1-2

Protocol Title:
A Single Center Prospective Comparative Study to Evaluate the performance of an Upper Torso Garment containing 100% Celliant Fibers that Emits Far Infrared (FIR) from Ceramic Particles contained within the Fibers in healthy subjects.

February 10, 2014

Hologenix, LLC

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Summary of Results for the Study HC1-2

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EXECUTIVE SUMMARY
Executive Summary

This Comparative performance evaluation was conducted in accordance with the protocol. The primary objective was met and showed that the upper torso garment containing 100% Celliant (180 g/m² Celliant Fabric) had higher readings of \( t_cP0_2 \) than the control (Non Celliant) group. The paired samples t-test reveals that the differences are significant at the 99% confidence level. The study protocol measured levels of \( t_cP0_2 \) as a surrogate for arterial perfusion using a cross over, repeated measures experimental design. Celliant was the Active fabric in this study while the Control is non-Celliant. This study was conducted from October through January of 2014 in Santa Monica, California.

During the design phase of this study, a One-Sample T-Test Power Analysis was conducted to determine the number of required participants needed to obtain reliable results and throughout the study subjects were screened to prevent oversample by gender, race, and age (must be 18-65).

A total of 153 usable subject tests were completed with local people who were recruited on-line and paid a $25 incentive as approved by the IRB.

The objective of Celliant is to improve perfusion and blood flow. The increased \( t_cP0_2 \) results represents an increase in the amount of oxygen diffusing outward across the skin and is used as a clinical surrogate for arterial perfusion. Other real time measurements such as body temperature and \%O_2 saturation were made.

Statistical testing reveals that subjects wearing the Active (Celliant) upper torso garment consistently have higher \( t_cP0_2 \) levels at the 30, 60, and 90-minute intervals than those wearing the Control (Non Celliant) fabric.

- The typical % of change between levels at each time increment ranges from 8.2% to 8.8%. The original estimate was that a 7% change would occur; therefore expectations were exceeded at every time increment tested.

- The most meaningful measure true \( t_cP0_2 \) change in this experiment, a Paired Samples T-Test reveals that differences between \( t_cP0_2 \) levels are significant at the 99% confidence level for each time increment.

- The Wilcoxon Signed Rank Test, run as an additional measure, also shows significant differences between the \( t_cP0_2 \) levels at every time increment.
The median age of respondents is 38.0, which is similar to the USA median of 36.8. Ethnic composure of subjects is 52% Caucasian, 22% African American, 16% Hispanic, 8% Asian, and 1% other. Compared to the USA totals this sample is slightly lower in Caucasian (64% USA vs. 52% experiment) and higher in African American (13% in USA vs. 22% experiment).

By gender:

- **Males:** are 54% of subjects, the average height of is 5'8", average weight is 184.5 pounds, have an average BMI of 26.9

- **Females:** are 46% of subjects, average height is 5'4", average weight is 146.8 pounds, and average BMI is 24.1.

- Overall, the **men** are **slightly shorter and lighter** with typical BMIs compared to the USA average while **females** are normal height and are **lighter** than USA averages.

The subject group as a whole had an average body temperature of 33.1 (C), an O$_2$ saturation of 98.0 and t$_c$P$_{O2}$ levels of 64.9.

- In general, t$_c$P$_{O2}$ **levels** are higher on average for females, those under 5'6" tall, and those who weigh less than 180 pounds.

- **Skin temperature** averages slightly higher for males, those 5'6" tall or higher and those with moderate weights (145-<180) and moderate BMIs (25-<30). Also, chair 1 had slightly higher average temperature readings.

- **O$_2$ saturation**, on average, is higher for females, lighter people, and those with low BMIs (<25). Also, some difference existed according to humidity (<35%) and chair 3 was slightly higher than chairs 1 and 2.

Statistical tabulations with a t-test for proportions and means were used to assess the potential impact of laboratory conditions on t$_c$P$_{O2}$ levels. This revealed that there is no significant difference between t$_c$P$_{O2}$ levels by the chair where the subject was seated, the temperature of the room, the humidity of the room, and the sequence of testing.

Finally, the **physical attributes of subjects** that typically impact t$_c$P$_{O2}$ levels demonstrated consistency throughout the testing, meaning that people were true to their traits and that the testing experience was similar for all participants.
Primary Outcomes

tcP0₂

The primary end point of this study was met. A paired sample t-test was conducted and the null hypothesis was rejected. This test reveals that the differences are significant at the 99% confidence level at all times. The average percentage change was greater than 8% at all three time points.
Background and Methodology

Background

Hologenix has developed and patented a proprietary fiber called Celliant that contains a matrix of ceramic particles within the fiber. It is designed to recycle and/or reuse radiant body heat into infrared that gives the body a measurable benefit.

Hologenix has organized seven completed clinical studies to date covering a variety of usage situations for Celliant. Initially the focus was to prove that Celliant increased tissue oxygen levels by measuring transcutaneous oxygen levels ($t_{cP02}$), a practice commonly used for people suffering from hypoxia, peripheral vascular disease or any other condition that inhibits blood flow.

The current study, testing Upper Torso Garments containing 100% Celliant fibers is designed to:

- capture and analyze the impact of wearing a Celliant garment on the upper torso at intervals of 30, 60, and 90 minutes,

- determine if significant differences in $t_{cP02}$ levels exist between the active (Celliant) and control fabrics.

Methodology

This clinical study was conducted at the company performance laboratory from October 2013 through January 2014. Subjects were recruited through an online advertising promotion and were paid a $25 incentive as approved by the IRB. Screening for age group (18 – 65), gender and race was used to provide balance and prevent oversampling of any particular demographic.

Room conditions were controlled and monitored to maintain consistent temperature and humidity levels and a total of 4 chairs were used for subjects to sit in during testing.

Exposure to Active vs. Control fabric was randomized using a pattern generated in SPSS and lab attendants received specific instructions for adhering to the pattern. This is a single-blind repeated measures study: subjects were unaware of active vs. control status and each subject is exposed to both the active and control fabric.

A predetermined rejection criterion was established prior to launching this study. Ultimately, a total of 21 subjects were removed from this clinical study due to
instrumental errors (unstable readings) arising from electrode membrane problems and related issues.

During the design phase of this study, a One-Sample T-Test Power Analysis was conducted to determine the number of required participants needed to obtain reliable results.

The total base size for this study is 153.
DETAILED FINDINGS
Subject Profile

This study was conducted in Santa Monica, CA where subjects were recruited locally through online advertising. Screening took place to prevent oversampling of any particular group. After the screening process and some data cleaning (related to faulty instrument readings) took place, a total of 153 subjects are included in the study.

- Just over one-half are male (54%) which is slightly higher than the composition of males in the United States (49.1% male).

- The remaining 46% are female which is slightly lower than the proportion in the United States (50.9%).

- The average height of males in this study is 5'8" which is slightly shorter than the national average of 5'9.5".

- Women in this study average 5'4" in height, which is also the national average.

- The average weight of women in this study is 146.8 lbs which is lower than the national average of 164.7 lbs.

- Men in this study average 184.5 pounds which is also lower than the national average of 194.7.

The median age of study participants is 38.0 which is only 1.2 years different from the median age of 36.8 in the United States.
Body Mass Index (BMI) is used to categorize people into healthy, overweight, and obese weight classes in the United States.

- Overall, the average BMI for study subjects is 25.7.
- Males in this study have an average BMI of 26.9 (USA is 26.6).
- Females subjects average 24.1 (USA is 26.5).

When it comes to race and ethnicity, the greatest proportion of subjects are white (52%) followed by African American (22%), Hispanic (16%), Asian (8%) and mixed or other (1%) and overall. While there are some differences, the subject group as a whole generally follows population trends within the United States.
Subject Readings During Set-Up

At the time the experiment was set-up, the subject group as a whole had an average **body temperature** of 33.1 °C, an **O₂% saturation** of 98.0 and **t_cP₀₂** levels of 64.9. Certain factors were found to have a relationship with an increased reading of these measures and are detailed in the chart below.

### Significantly Higher Readings by Group or Situation

<table>
<thead>
<tr>
<th>Skin Temperature (°C)</th>
<th>0₂% Saturation</th>
<th>t_cP₀₂</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Males</strong></td>
<td><strong>Females</strong></td>
<td><strong>Females</strong></td>
</tr>
<tr>
<td>[33.3 male vs. 32.9 female]</td>
<td>[98.5 female vs. 97.6 male]</td>
<td>[70.3 female vs. 60.2 male]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Height is 5.6&quot;+</th>
<th>--</th>
<th>Height &lt;5.6&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>[33.3 5'6+ vs. 32.8 &lt;5'6&quot;]</td>
<td>--</td>
<td>[70.2 vs. 61.2-62.3]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Moderate Weight (145 - &lt;180)</th>
<th>Decreasing Weight</th>
<th>Weight &lt;180 Lbs</th>
</tr>
</thead>
<tbody>
<tr>
<td>[33.4 145-180 lbs vs. 32.9 &lt;145]</td>
<td>[98.4 &lt;180 lbs vs. 97.3 180 lbs+]</td>
<td>[98.4 vs. 97.26 at 180+]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BMI MODERATE 25 - &lt;30</th>
<th>BMI Lowering to &lt;25</th>
<th>--</th>
</tr>
</thead>
<tbody>
<tr>
<td>[33.5 vs. 33.0 at low BMI vs. 32.9 at high BMI]</td>
<td>[98.4 vs. 97.8 at moderate BMI vs. 96.9 at high BMI]</td>
<td>--</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Room Temp (24+ °C)</th>
<th>Lower Humidity &lt;35%</th>
<th>--</th>
</tr>
</thead>
<tbody>
<tr>
<td>[33.7 vs. 32.9 at &lt;24 (°C)]</td>
<td>[98.4% vs. 97.8 at 35%+]</td>
<td>--</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chair 1</th>
<th>Chair 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>[33.5 Chair 1 vs. 33.0-33.1 All Others]</td>
<td>[98.5 vs. 97.7-9 Chairs 1 &amp; 2]</td>
</tr>
</tbody>
</table>

*Low BMI within these subjects is considered <25, moderate is 25 - <30 and high is 30+.*

Base Size: 153
Clinical Environment

This experiment was designed with specific controls to eliminate extraneous variables that would create any inconsistency in the clinical study. The following controls and measures were present:

- Investigators followed a randomization schedule for handing out the first upper torso garment to be tested so that an appropriate balance of exposure to Active vs. Control was achieved in a non-biased fashion.

- Ultimately, 52% of subjects received the active garment first and 48% received the control garment first. [As shown on chart on this page].

The laboratory was controlled for a consistent temperature that did not vary more than 5 degrees throughout the entire experiment, ranging from 20.8 - 25.7 (°C).

Room humidity was also measured each time a subject arrived at the clinical laboratory for testing and was about 37.1% on average with a range from 26% to 50%. 
Active vs. Control Impact on \( t_cP_0^2 \) Levels

The aim of Celliant is to improve perfusion and blood flow, a surrogate measurement of \( tcP02 \) was used for assessing the benefits that will ultimately be provided to the user.

A simple overview of average \( t_cP_0^2 \) readings at 30, 60, and 90-minute intervals, plotted in the chart below, demonstrates that the active garment consistently yields higher levels than does the control garment.
Percentage Change In $t_cP_0^2$ Levels

The **percentage difference** that occurs in $t_cP_0^2$ levels is calculated using the following formula:

$$\frac{\text{ACTIVE} - \text{CONTROL}}{\text{CONTROL}} \times 100\%$$

Because this is calculated on a case by case basis, the numbers are averaged to find the overall estimate of Active vs. Control when it comes to $t_cP_0^2$ levels.

The average percentage change ranges from 8% to 9% when viewed at 30, 60, and 90 minute Active and control intervals.

Details from the calculation are below, the minimum and maximum figures are derived from individual cases while the standard deviation and mean are aggregated values.

<table>
<thead>
<tr>
<th>Increment</th>
<th>N</th>
<th>MINIMUM</th>
<th>MAXIMUM</th>
<th>STD. DEV</th>
<th>MEAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 Minute Increment</td>
<td>153</td>
<td>-.47</td>
<td>.84</td>
<td>.217</td>
<td>8.2</td>
</tr>
<tr>
<td>60 Minute Increment</td>
<td>153</td>
<td>-.37</td>
<td>.97</td>
<td>.206</td>
<td>8.8</td>
</tr>
<tr>
<td>90 Minute Increment</td>
<td>153</td>
<td>-.32</td>
<td>.89</td>
<td>.181</td>
<td>8.5</td>
</tr>
</tbody>
</table>
**t_cP0₂ Paired Sample T-Test Results:**

In order to determine whether a true statistically significant difference exists between $t_cP0₂$ levels in subjects wearing the Active and Control fabric, a **paired samples t-test** was conducted. This test is ideal for this situation because we are interested in comparing the means from two sets of observations where variables are not entirely independent due to the fact that we are looking at a repeated measures experiment.

Specific data resulting from the Paired Samples T-Test is below:

<table>
<thead>
<tr>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>99% Confidence Interval of the Difference</th>
<th>Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 MINUTE</td>
<td>3.4209</td>
<td>11.2890</td>
<td>.9127</td>
<td>1.0402</td>
</tr>
<tr>
<td>60 MINUTE</td>
<td>4.2967</td>
<td>10.1583</td>
<td>.8212</td>
<td>2.1545</td>
</tr>
<tr>
<td>90 MINUTE</td>
<td>1.8373</td>
<td>3.4731</td>
<td>.2808</td>
<td>1.1048</td>
</tr>
</tbody>
</table>

This test reveals that **differences are significant at the 99% confidence level** indicating that $t_cP0₂$ differences are statistically meaningful when comparing the Active to the Control during all time periods.

Therefore, the null hypothesis is rejected in all pairs and the alternative hypothesis is found to be true. **[Null Hypothesis: Mean0=Mean1  Alternative Hypothesis: Mean0≠Mean1]**

Note: Degrees of freedom=152 for all pairs.
**t_cP_0_2 Related Samples Wilcoxon Signed Rank Test**

**RESULTS SUMMARY**

The **Wilcoxon Signed Rank Test** is used to test repeated measurements on a single sample to assess whether their population mean ranks differ (i.e. it is a paired difference test). It can be used as an alternative to the paired Student's t-test, t-test for matched pairs, or the t-test for dependent samples when the population cannot be assumed to be normally distributed.

This is a non-parametric test which means that data is not *required* to satisfy the normality assumption. Since there are fewer assumptions for rank based tests and they perform almost as well as, and often much better than, parametric tests.

When tested using this measure using a median of differences, t_cP_0_2 levels are found to be significantly different at the 99% confidence level during all time increments tested (30, 60, and 90 minutes).

<table>
<thead>
<tr>
<th>Hypothesis Test Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Null Hypothesis</td>
</tr>
<tr>
<td>The median of differences between CONTROL 30 MIN TCPO2 and ACTIVE 30 MIN TCPO2 equals 0.</td>
</tr>
</tbody>
</table>

Asymptotic significances are displayed. The significance level is .01.

<table>
<thead>
<tr>
<th>Hypothesis Test Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Null Hypothesis</td>
</tr>
<tr>
<td>1 The median of differences between CONTROL 60 MIN TCPO2 and ACTIVE 60 MIN TCPO2 equals 0.</td>
</tr>
</tbody>
</table>

Asymptotic significances are displayed. The significance level is .01.

<table>
<thead>
<tr>
<th>Hypothesis Test Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Null Hypothesis</td>
</tr>
<tr>
<td>1 The median of differences between CONTROL 90 MIN TCPO2 and ACTIVE 90 MIN TCPO2 equals 0.</td>
</tr>
</tbody>
</table>

Asymptotic significances are displayed. The significance level is .01.
Related Samples Wilcoxon Signed Rank Test
30 MINUTE TIME INTERVAL

The median of differences between Active and Control is significant at the 99% confidence level.

<table>
<thead>
<tr>
<th>Null Hypothesis</th>
<th>Test</th>
<th>Sig.</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>The median of differences between CONTROL 30 MIN TCPO2 and ACTIVE 30 MIN TCPO2 equals 0.</td>
<td>Related-Samples Wilcoxon Signed Rank Test</td>
<td>.000</td>
<td>Reject the null hypothesis.</td>
</tr>
</tbody>
</table>

Asymptotic significances are displayed. The significance level is .01.

Active garment yields positive increases in \( t_{\text{pO}_2} \) levels in 63% of subjects tested.
Related Samples Wilcoxon Signed Rank Test
60 MINUTE TIME INTERVAL

The median of differences between Active and Control at the 60 minute time interval is significant at the 99% confidence level.

<table>
<thead>
<tr>
<th>Null Hypothesis</th>
<th>Test</th>
<th>Sig.</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>The median of differences between CONTROL 60 MIN TCPO2 and ACTIVE 60 MIN TCPO2 equals 0.</td>
<td>Related-Samples Wilcoxon Signed Rank Test</td>
<td>.000</td>
<td>Reject the null hypothesis.</td>
</tr>
</tbody>
</table>

Asymptotic significances are displayed. The significance level is .01.

The majority of unique cases, 68%, show positive difference (increases) in $t_cP_02$ levels between Control and Active at the 60 minute mark.
**Related Samples Wilcoxon Signed Rank Test**

**90 MINUTE TIME INTERVAL**

The median of differences between Active and Control is significant at the 99% confidence level.

<table>
<thead>
<tr>
<th>Null Hypothesis</th>
<th>Test</th>
<th>Sig.</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>The median of differences between CONTROL 90 MIN TCPO2 and ACTIVE 90 MIN TCPO2 equals 0.</td>
<td>Related-Samples Wilcoxon Signed Rank Test</td>
<td>.000</td>
<td>Reject the null hypothesis.</td>
</tr>
</tbody>
</table>

Asymptotic significances are displayed. The significance level is .01.

The majority of unique cases, 71%, show increases in $t_cP_0$ levels when subjects are wearing the Active garment 90 minute mark.
**t_cP0_2 LEVELS IN THE STUDY ENVIRONMENT**

Statistical tabulations were used to assess any possible relationship between differences in Active and Control t_cP0_2 levels and laboratory conditions.

A specific t-test for proportions and means was conducted at the 95% confidence level (although it is not to say that these results may be significant at the 99% level as well).

This analysis reveals that:

- ✓ **There is no significant difference in TCPO2 levels by the chair** the subject sat in; therefore, we can safely say that seating was consistent in terms of the subject experience.

- ✓ **The temperature of the room** had no bearing on t_cP0_2 levels.

- ✓ **The humidity of the room** did not impact presence of t_cP0_2 levels.

- ✓ **The sequence of testing** did not impact t_cP0_2 levels.

- ✓ **Finally, physical attributes of subjects** that typically impact t_cP0_2 levels demonstrated consistency throughout the testing, meaning that people were true to their traits and that the testing experience was the similar for all participants.
References


