Michael J. Buono, Ph.D.
San Diego State University
School of Exercise and Nutritional Sciences and the
Department of Biology

Date: January 29, 2015

Cardiovascular Research Study Summary
The AVACEN Treatment Method (ATM)

Investigators: Michael J. Buono, Ph.D., Doug Jones, M.S., Carina Pautz, B.S.

Facility: San Diego State University, School of Exercise and Nutritional Sciences, Exercise Physiology Lab

IRB: Approved by the San Diego State University Institutional Review Board

Introduction: The AVACEN Treatment Method (ATM) uses active heat assisted by negative pressure applied noninvasively to the palm of the hand for a predetermined therapeutic protocol of between 10 and 30 minutes.

Investigational Device: The AVACEN 100 uses the AVACEN Treatment Method (ATM). The ATM technology platform uses a microprocessor controlled chamber to surround the hand with a slight negative pressure, while adding heat to the palm. This negative pressure increases the volume of blood in the palm's unique vascular networks while heat is simultaneously transferred from the microprocessor managed palm pad into this expanded vascular system. The AVACEN 100 is a non-invasive class II medical device that is cleared by the FDA as a heat therapy system indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains; muscular relaxation; and the temporary increase of local circulation where applied. The FDA has not cleared the AVACEN 100 as safe and effective for the treatment of cardiovascular disease.

Objective: Assess cardiovascular dynamics during 30 minutes of the AVACEN Treatment Method (ATM).

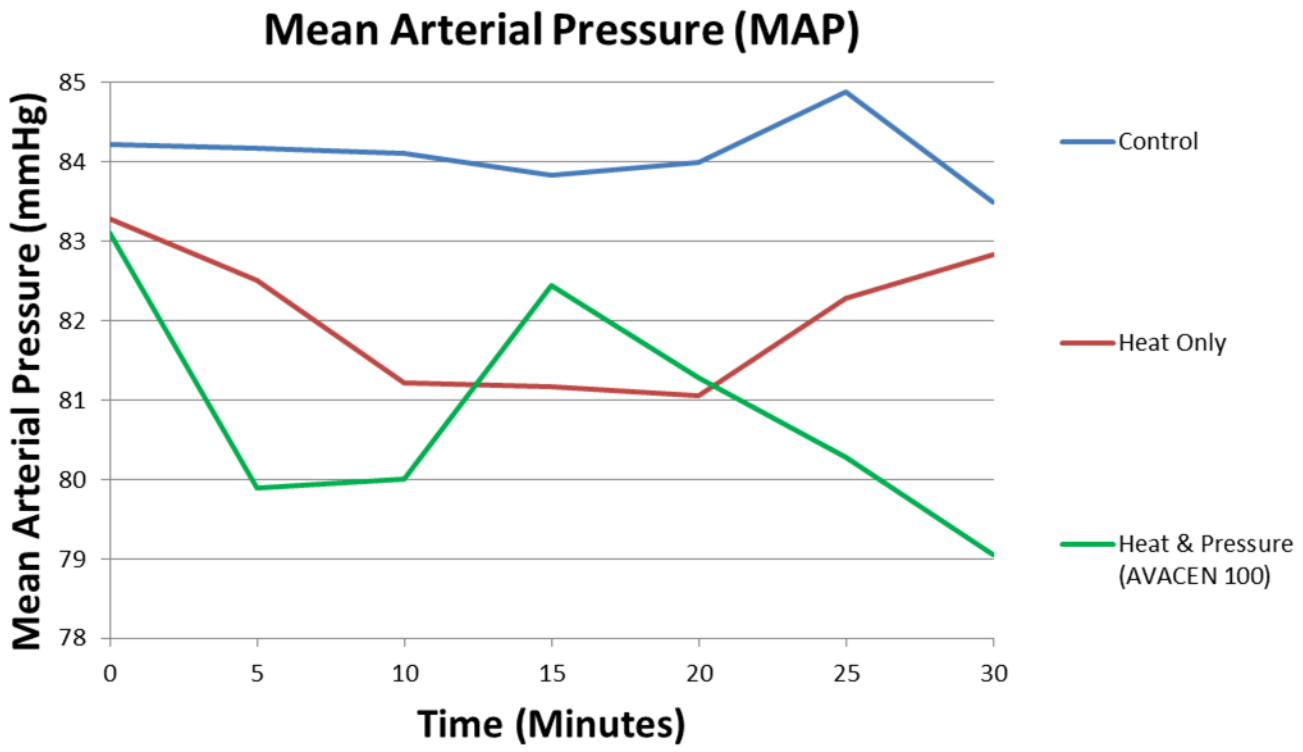
Design: Randomized, single-blind and placebo-controlled trial.

Subjects: 6 participants (2 Female, 4 Male). Age range was 24 to 59 years old (X=31 years). Subject BMI range was 20 to 27 (X=22).

Methods: All subjects were randomized and underwent three independent treatment sessions for 30 minutes using each treatment method: Heat and Negative Pressure, Heat Only, and Placebo Control. Treatment sessions were administered on separate days. An automated blood pressure monitor was applied to the opposite treatment arm to measure mean arterial pressure (MAP). An oral thermometer was utilized to measure body temperature. Electrodes were applied to the neck and abdomen region to measure heart rate and stroke volume. All measurements were administered every five minutes. Two baseline measurements were taken for all cardiovascular variables and their mean was calculated to determine the resting starting point (minute-zero).

The “heat and negative pressure” treatment session consisted of 40-43°C heat and a negative pressure vacuum of -30 mmHg. The “heat only” treatment session consisted of 40-43°C heat and zero negative pressure. The “placebo control” treatment session consisted of minimal heat to mimic room temperature and zero negative pressure. The device motor was running during all three session conditions.

Results: The “heat and negative pressure” treatment session using the AVACEN 100 demonstrated that mean arterial pressure (MAP) was significantly reduced ($P<0.05$) from a mean of 83 mmHg at rest to a mean of 79 mmHg at 30 min on heat/negative pressure. Repeated measures of Analysis of Variance (ANOVA) and Tukey post-hoc comparisons were used to analyze the mean MAP. Statistical significance was seen at both the 5 minute and 30 minute treatment time compared to the minute-zero resting baseline values. In addition, the “control” and “heat only” trials showed no significant decrease in MAP over the 30 minutes.



Conclusion: The AVACEN Treatment Method (ATM) demonstrated a significant reduction in MAP after 5 and 30 minutes of therapy. Future research should examine how long after a “heat and negative pressure” treatment the decrease in MAP lasts.

Michael J. Buono, Ph.D., is a full professor at SDSU and has over 30 years of experience conducting studies in the area of exercise physiology, thermoregulation, body temperature control, endocrine sweat gland physiology, and cardiovascular dynamics. Dr. Buono has a B.S., M.Ed. and Ph.D., and has over 100 publications in the scientific literature.

AVACEN Medical funded this study via a grant to the San Diego State University Research Foundation.

The FDA has not cleared the AVACEN 100 as safe and effective for the treatment of cardiovascular disease.

AVACEN, Inc. 7920 Silverton Ave. Suite L, San Diego, CA 92126 (888) 4-AVACEN Fax (888) 428-2236