A Randomized, Controlled, Feasibility Trial to Evaluate the Effectiveness of High-Pressure, Rapid Sequence, Intermittent Pneumatic Calf and Foot Compression (HPIPC*) for the Treatment of Intermittent Claudication, Pain and Ulcer Healing in Subjects with Mild to Moderate Peripheral Arterial Occlusive Disease (PAOD).

Oscar M. Alvarez, PhD, Martin Wendelken, DPM, RN, Lee Markowitz, DPM, Christopher Comfort, MD., Center for Curative and Palliative Wound Care, Calvary Hospital, Bronx, NY., Department of Medicine, New York Medical College, Valhalla, NY

Twelve subjects with symptomatic mild to moderate PAOD (claudication pain, resting pain, numbness and lower leg ulceration were enrolled in a feasibility study from a single clinical center and randomized into 2 treatment groups. Six subjects received treatment with HPIPC (60 minutes twice daily for 8 weeks) and 6 subjects received standard care consisting of an exercise regimen (brisk walking for 20 minutes twice daily for 8 weeks). The HPIPC device delivers bilateral pressures of 120mmHg. Cycle times provide sequential compression for 3 seconds (+/-0.5 sec.) followed by a 17 second rest period (+/-3.0 sec.), resulting in a 20 second cycle or 3 cycles per minute. The primary endpoint was peak walking time (PWT, time to maximally tolerated claudication pain). Secondary endpoints were change in resting ABIs, ulcer healing, intensity of wound pain, relief of pain and quality of life index (QOL). Age (71.2 vs. 70.7), baseline PWTs (4-9 minutes) and risk factors were similar in both treatment groups. At 4 weeks the percent change from baseline in PWT were did not vary significantly between treatment groups (19.9 for HPIC and 18.45 for standard care). However after 8 weeks the percent change in PWT for the HPIPC group was 64.68 compared to 37.4 for the group receiving standard care ($p<0.05$). Greater improvement in mean ABIs was observed in the HPIPC group (5.89 at week-4 and 7.0 at week 8). The time to 50% ulcer healing was 4.8 weeks for the HPIPC group and 7.3 weeks for those receiving the exercise regimen. When compared to the standard care group, the HPIPC group reported less pain and greater pain relief at week 4 and week 8. HPIPC was well tolerated and simple to use. Study of HPIPC in a larger patient population is underway.

*BioArterial Plus Bio Compression Systems, Inc., Moonachie, NJ