

Clinical References

¹A RANDOMIZED TRIAL OF CLASS 2 AND CLASS 3 ELASTIC COMPRESSION IN THE PREVENTION OF RECURRENCE OF VENOUS ULCERATION

Two year follow-up results presented American Venous Forum, February 2009 by Dr. D. Milic

In February 2009, Dr. Dragan Milic provided the answer to this question at the American Venous Forum meeting. Dr. Milic reported the two year follow-up results of over 320 venous stasis ulcer patients that were healed with compression bandaging and then were placed in compression stockings that provided A) an average of 25 mmHg compression at the ankle or B) an average of 40 mmHg compression. 1 out of 4 patients that received stockings that provided 25 mmHg had their ulcers come back during the 2 year period. While those who wore 40 mmHg compression stockings reduced the recurrence by 50%.

²JUXTA-LITE™ PROVIDES RELIABLE, REPEATABLE GRADIENT COMPRESSION

Inelastic compression legging produces gradient compression and significantly higher skin surface pressures compared with an elastic compression stocking. Kline CN, Macias BR, Kraus E, Neuschwander TB, Angle N, Bergan J, Hargens AR. Published in *Vascular*, Volume 16, No. 1, 2008

Summary: This study compared skin surface pressures underneath the inelastic CircAid® garment with Built-In Pressure System™ set to 40 mmHg vs. an elastic 30-40mmHg below-knee compression stocking. The CircAid® leggings produced significantly higher skin pressures than elastic leggings at both leg regions ($p < .001$). Mean pressures over all trials using the CircAid® leggings were 47 ± 3 and 35 ± 2 mmHg for ankle and below-knee regions, respectively. Mean pressures using the elastic leggings over all trials were 26 ± 2 and 23 ± 1 mmHg for ankle and below-knee regions, respectively. Only the CircAid® leggings produced a significant reverse-pressure gradient between the knee and the ankle ($p < .05$), whereas the elastic leggings did not.

³INELASTIC COMPRESSION INCREASES THE HEALING RATE OF VENOUS ULCERS COMPARED TO MULTI-LAYERED BANDAGING

Comparison of elastic versus nonelastic compression in bilateral venous ulcers: a randomized trial. Blecken SR, Villavicencio JL, Kao TC. Published in *Journal of Vascular Surgery*, December 2005.

Summary: The completed study comparing 24 extremities shows that at three months, patients wearing the inelastic CircAid® system had significantly faster ulcer healing rates as compared to patients wearing a conventional four layer elastic compression system.

⁴UTILIZING JUXTA-LITE™ CAN REDUCE THE COST OF PATIENT CARE

Comparison of Costs and Healing Rates of Two Forms of Compression in Treating Venous Ulcers. RG DePalma, M.D., RK Spence, M.D., JA Caprini, M.D., MR Nehler, M.D., J. Jenson, D.P.M., MP Goldman, M.D. Published in *Journal of Vascular Surgery*, November 1999 Volume 33 Number 6.

Summary: The total cost of treatment was 38% less with the CircAid® Legging and this difference was statistically significant. Healing rates were 45% faster with CircAid® garment, though this value did not reach statistical significance because of large standard deviations. Presented at the eleventh annual meeting of the American Venous Forum, February 18-21, 1999 Dana Point, CA.

⁵INELASTIC COMPRESSION REDUCES EDEMA MORE THAN ELASTIC COMPRESSION

Inelastic versus elastic leg compression in chronic venous insufficiency: a comparison of limb size and venous hemodynamics. Spence RK, Cahall E. Published in *Journal of Vascular Surgery*, November 1996 Volume 24 Number 5.

Summary: This study compared the ability of 30-40 mmHg below-knee compression stockings to the CircAid® compression garment to reduce and maintain limb circumference and to improve abnormal venous hemodynamics in 10 patients (20 limbs) with Class III CVI, defined by history, air plethysmography (APG) chronic stasis and/or ulceration. APG studies plus ankle/calf measurements were taken on separate days with no compression (B), stockings (S) and the CircAid® garment. Tests were performed at two and six hours after patients had donned new garments. Results were analyzed using non-parametric measures because of sample size.

Conclusions: In this small group of patients, the CircAid® compression garment was superior to stockings in reducing and maintaining limb circumference and venous volume while decreasing reflux and improving hemodynamics in Class III CVI patients. Presented at the 8th Annual Meeting Of The American Venous Forum, February 22-24, 1996 San Diego, CA.

⁶INELASTIC COMPRESSION IS SAFER FOR 24-HOUR USE COMPARED TO ELASTIC STOCKINGS

Intramuscular pressures beneath elastic and inelastic leggings. Murthy G, Ballard RE, Breit GA, Watenpaugh DE, Hargens AR. Published in *Annals of Vascular Surgery*, November 1994 Volume 8 Number 6.

Summary: Alan R. Hargens, Ph.D., physiologist and Space Station Project Scientist, in developing garments to combat the effects of microgravity in space on astronauts, directed two studies. The results of one study have been published in the *Annals of Vascular Surgery*, November 1994, entitled, "Intramuscular Pressures Beneath Elastic and Inelastic Leggings". The studies compared the effects of the inelastic CircAid® Legging and 30-40mmHg elastic stockings on Intramuscular pressures (IMP) in soleus and tibialis muscles taken by catheter inserted pressure transducers. IMPs, which are more relevant to tissue nutrition and venous return than surface or subcutaneous pressures, taken on 10 healthy subjects, were significantly higher with the inelastic legging than with elastic stockings. During recumbency, elastic stockings produced high surface compression. The inelastic legging did not exert such high surface compression, yet effectively generated high IMPs during standing and walking.

⁷COMFORT CAPRI™ PREFERRED OVER THIGH-HIGH ELASTIC COMPRESSION STOCKINGS BY POST VEIN ABLATION PATIENTS

John Mauriello MD, Teresa Kennerknecht, Cardiovascular and Vein Center of Florida. Pilot Study, July 2011

Summary: A pilot study to determine the suitability of the Comfort Capri™ as a compression device following great saphenous vein (GSV) ablation procedures. Comfort Capri™ and thigh-high compression stockings were applied on 7 women who underwent bi-lateral GSV ablation. Each leg was treated individually with a 7-10 day waiting period between procedures. Patients ranged in age of 40 to 65 years and were randomized to wear the Comfort Capri™ or the stocking for the first treatment, then were asked to wear the other garment for comparison following the second treatment. The Comfort Capri™, which covers from below the knee to the waist, and the thigh-high elastic compression stocking were worn for an average of 5 and 4 days, respectively. Evaluated aspects included application, removal, fit, pain level, comfort, adhesiveness, and overall quality. Five of the six patients preferred the Capri over the stocking and the remaining patient did not have a preference. Patients reported that the Comfort Capri™ was easier to apply, was more comfortable, offered a better fit, and stayed in place better than the compression stocking. One patient was excluded from the comparative data as she did not wear both garments, but nevertheless rated the Capri's features as being excellent. This small pilot study suggests a strong trend towards patients preferring the Comfort Capri™ for compression instead of compression stockings after GSV ablation treatment. The Capri received an equal or better rating in all categories, which suggests that patients prefer the Capri as a compression solution over the elastic stocking.