

# ***Improvement in Clinical Outcomes, Physical Function, and Bodily Pain Following a 12 Week Course of Intermittent Pneumatic Compression (IPC) in Patients with Chronic Venous Ulcers: Results of an Observational Longitudinal Retrospective Study***

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Treatment Strategies for Patients with Lower Extremity Chronic Venous Disease



# DISCLOSURE

## RESEARCH SUPPORT

- New York State Department of Health (>\$10,000)
- Medline, Inc (>\$10,000)

## CONSULTING

- Advisory Boards:
- Molnlycke USA Wound Care Advisory Panel (<\$10,000)
- BioCompression Systems Inc (>\$10,000)
- Sun Scientific Inc (>\$10,000)

## COMMITTEES

- International Compression Club
- Venous Forum

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# Improvement in Clinical Outcomes, Physical Function, and Bodily Pain Following a 12 Week Course of Intermittent Pneumatic Compression Therapy in Patients with Chronic Venous Ulcers: Results of an Observational Longitudinal Retrospective Study

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# BACKGROUND

- Clinical records of 94 chronic venous ulcer patients (treated at 2 independent specialty centers) were included in a retrospective analysis to evaluate the effects of standard of care plus continued Intermittent Pneumatic Compression (IPC) therapy during and after wound closure.

# METHODS

- Both clinical centers employed the Venous Clinical Severity Score (VCSS) to monitor clinical outcomes.
- IPC application was with a 4 chamber gradient IPC at 55mmHg for 1 hour BID using standard adjustable (95.3cm) half leg sleeves. Both Centers used the same IPC therapy pump (Bio Compression Model 2004, Bio Compression Systems Inc. Moonachie, NJ).
- IPC was applied on top of standard compression bandages
- All patients were seen weekly for standard evaluations and reapplication of compression bandages.
- Patient record analysis was for 12 consecutive weeks beginning at baseline (prior to IPC application). VCSS scores were recorded at monthly intervals.

# STATISTICS

- Summary statistics (means and standard deviations [SD] for continuous variables and frequency distribution for categorical variables) were used to describe the sample.
- To evaluate the association between degree of pain and other outcomes we used Kuskal-Wallis to measure for continuous outcomes and Chi-square or Fisher's Exact tests for categorical outcomes.
- Statistical significance was set at 0.05

**Table 1. Demographics and clinical characteristics, overall and from each clinical center**

Variable	Clinical Site #1	Clinical Site #2	Pooled Demographics
Mean age (years)	74.6	64.4	69.5
Sex (% female)	53.2	55	54.1
Ulcer duration (months)	7.2	12.5	9.8
Baseline ulcer size (cm <sup>2</sup> )	18.5	26.3	22.4
Non-ambulatory (%)	0	23.5	11.7
>1 Ulcer (%)	21.6	32.3	26.5
Mean BMI	30.8	34.4	32.6

# Table2. Pooled VCSS Scores at Baseline (prior to treatment with IPC) and Week-12

Symptom	Baseline	12-Weeks	P-Value*
<b>Pain</b>			
<i>Severe</i>	42 (44.6%)	0	0.004
<i>Moderate</i>	17 (18%)	8 (8.5%)	0.051
<i>Mild</i>	22 (23.5%)	10 (10.6%)	0.59
<i>None</i>	13 (13.8%)	76 (80.8%)	0.001
<b>Edema</b>			
<i>Severe</i>	63 (67%)	0	0.07
<i>Moderate</i>	22 (23.4%)	13 (13.8%)	0.082
<i>Mild</i>	9 (9.5%)	14 (14.8%)	0.27
<i>None</i>	0	67 (71.2%)	0.004
<b>Inflammation</b>			
<i>Severe</i>	28 (29.7%)	0	0.022
<i>Moderate</i>	54 (57.4%)	3 (3.1%)	0.018
<i>Mild</i>	12 (12.7%)	31 (32.9)	0.16
<i>None</i>	0	60	0.001
<b>Induration</b>			
<i>Severe</i>	13 (13.8%)	6 (6.3%)	0.146
<i>Moderate</i>	38 (40.4%)	29 (30.8%)	0.29
<i>Mild</i>	43 (45.7%)	34 (36.1%)	0.09
<i>None</i>	0	25 (26.5%)	0.041
<b>Active Ulcers</b>			
<i>Severe (≥3)</i>	5 (5.3%)	0	0.066
<i>Moderate (2)</i>	16 (17.0%)	2 (2.1%)	0.059
<i>Mild (1)</i>	73 (77.6)	17 (18.0%)	0.037
<i>Healed</i>		75 (80%)	0.002

# Conclusions

- The incidence of ulcer healing was 80% after 12 weeks of IPC therapy.
- Symptomatic improvement was noted in every VCSS parameter measured.
- In the category of pain, there was a significant difference in the number of patients reporting severe pain before and after IPC therapy (42 at baseline vs. 0 after 12 weeks of IPC [ $p=0.004$ ]).
- Also the number of patients reporting no pain before and after IPC therapy increased by 67% ( $p<0.001$ ).

## Conclusions (cont'd)

- In the category of edema, significant improvement was noted after 12 weeks of IPC therapy in patients that had severe edema at baseline ( $p=0.017$ ) and also in the number of patients where the edema resolved ( $p=0.004$ ).
- Severe inflammation was significantly reduced in all study patients ( $p=0.022$ ) and completely resolved in 60 of the 94 patients (63.8%,  $p<0.001$ ).