Prospective, multicenter, randomized controlled trial comparing a new two-component compression system, to zinc-oxide bandage in venous leg ulcers.

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Key Finding:

3M[™] Coban[™] 2 Layer Compression System delivers comfortable, skin friendly, sustained compression supporting edema reduction and venous leg ulcer wound healing.

Purpose:

The purpose of this study was to clinically compare two compression bandages, $3M^{TM}$ CobanTM 2 Layer Compression System and a 4 layer Unna boot* for venous leg ulcer healing, condition of surrounding skin, pain, and quality of life. In addition, bandage parameters of the study included resting pressures and static stiffness indices (SSIs) taken at B1 site at application and prior to removal at 7 days, slippage, edema reduction, ease of application and removal.

Methodology:

- 100 participants with venous leg ulcers were enrolled and randomized to one of two bandages: Coban 2 Layer Compression System or Unna boot. Patients were followed weekly for three months.
- Ulcer treatment was the same for all patients. 3M[™] Cavilon[™] No Sting Barrier Film used as needed to protect the periwound area and 3M[™] Tegaderm[™] Foam Dressing (nonadhesive) as a primary wound dressing.
- Primary endpoints of the study included both ulcer area and ulcer healing time, wound bed status, exudate and surrounding skin status as well as bandage parameters, including ease of application and removal, slippage, resting pressures at B1 and static stiffness indices, reduction of edema, pain and quality of life assessments.

Results

- Coban 2 Layer Compression System was effective in reducing edema and associated with 100% wound healing, 94% within the first three months of treatment not statistically different (91.8%) from the Unna boot.
- Coban 2 Layer Compression System delivered substantially equivalent, sustained, high stiffness over 7-day wear time.
- Coban 2 Layer Compression System reduced pain and improved patient quality of life.
- Coban 2 Layer Compression System has a comparable efficacy but is easier to apply and remove.
- Coban 2 Layer Compression System is comfortable to wear and is skin friendly.

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