Flexitouch® Demonstrates Greater Reduction in Limb Volume and Edema When Compared to a Simple Pneumatic Compression Pump

OBJECTIVE
The objective of this prospective, randomized trial was to investigate whether the Flexitouch system (HCPCS E0652), an advanced pneumatic compression device (APCD), provides better outcomes than a simple pneumatic compression device (SPCD), the Bio Compression 2004 (HCPCS E0651), in reducing arm volume in patients suffering from, unilateral, upper extremity, breast cancer-related lymphedema (BCRL).

METHODS
- 36 subjects were enrolled (18 per group) who had at least 5% arm edema volume who had previously completed intensive phase I in-clinic lymphedema treatment and were discharged to at-home self-management
- Subjects were randomly assigned to receive either the Flexitouch system APCD or the Bio Compression 2004 SPCD
- Subject arm volume, edema percentage and tissue dielectric constant, which measures local tissue water (LTW) volume of the affected and non-affected arms, were measured pre-device treatment and after 12 weeks of device treatment

RESULTS
- Subjects treated with Flexitouch APCD demonstrated a reduction in arm edema volume, percentage edema volume and LTW at 12 weeks which was improved from baseline. SPCD therapy resulted a net increase in edema volume and LTW. The difference in outcomes between treatment groups was statistically significant.
- Both groups had similar compliance with treatment, exercise, daily compression, self-massage and skin care
- Six complications were seen in the SPCD group compared with only one in the Flexitouch APCD group

DISCUSSION
Results of this randomized, controlled study suggest that application of the Flexitouch system APCD provides better outcomes as measured by significant arm edema and tissue water reductions combined with fewer complications compared to the SPCD group.

The SPCD takes 72 seconds to inflate and holds inflation for 22 seconds before deflating all chambers simultaneously. This process uses high pressures that may compress lymphatic capillaries beyond the range of therapeutic value and thereby prevent lymph uptake.\textsuperscript{1,2,3}
The Flexitouch system APCD uses inflation/deflation cycles of 1–3 seconds per chamber which is consistent with pressures described to increase lymph drainage in association with MLD.\textsuperscript{4,5} The dynamic, variable pressure of Flexitouch likely induces the initial lymph capillaries to respond to pressure changes in the skin and better corresponds to arterial and respiratory pulses which are thought to stimulate lymphatics\textsuperscript{1,6}

**CONCLUSION**

Data from this randomized, controlled trial demonstrates that treatment with the Flexitouch system provides better outcomes than simple PCD use in the treatment of breast cancer related lymphedema. Patients treated with Flexitouch demonstrated improvements in limb edema and LTW over 12 weeks. Flexitouch patients achieved better outcomes and the difference was statistically significant when compared to patients treated with a simple PCD.

**KEY POINTS**

- Findings suggest Flexitouch provides better treatment outcomes than use of a simple pneumatic compression device in the treatment of BCRL
- The Flexitouch system has demonstrated statistically significant improvements in limb volume, edema percentage and tissue water content at 12 weeks with fewer complications compared to the effects of a simple PCD
- These findings suggest clinical significance as previous studies’ have shown that even a 5% difference in limb volume can have a clinically significant reduction in the signs and symptoms of lymphedema in BCRL patients and likely positively impacts patient quality of life

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**References**