Flexitouch® System Reduces Limb Volume; Improves Quality of Life in Lower Extremity Lymphedema

Original Article:	Pneumatic Compression Device Treatment of Lower Extremity Lymphedema Elicits Improved Limb Volume and Patient-Reported Outcomes
Journal:	*European Journal of Vascular and Endovascular Surgery*
Publication Date:	2013 (Volume 46, Number 4) Oct;46(4):480–7.
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OBJECTIVE

One of the largest studies to assess pneumatic compression device (PCD) treatment outcomes in lower extremity lymphedema patients, this study examined the effect of Flexitouch system treatment on limb volume and quality of life outcomes such as pain reduction and increased function with activities of daily living (ADLs).

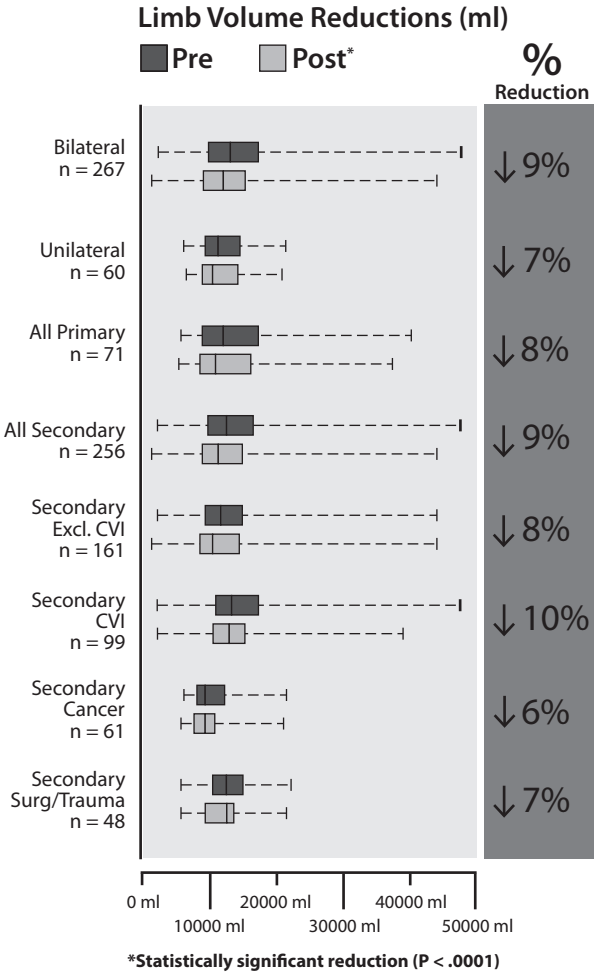
METHODS

Data was analyzed from 196 lower extremity lymphedema patients (327 limbs) with stage II (or greater) lymphedema who had been prescribed the Flexitouch system after completing therapist administered complete decongestive therapy (CDT). Data was captured to evaluate change in limb volume, patient-reported outcomes pre and post-treatment and clinician-reported post-treatment outcomes. Follow-up clinical assessment and limb measurements were obtained approximately 60 days after initiation of treatment. The Flexitouch system treatment program and frequency varied based on prescribed protocol. Sub-analyses were also performed to identify factors that may predict treatment response.

RESULTS

Use of the Flexitouch system to treat lower extremity lymphedema was associated with statistically significant reduction in limb volume, improvement in quality of life and no significant adverse effects.

- 88% of patients experienced a significant reduction in limb volume. 35% had limb volume reduction of greater than 10%. Mean limb volume reduction was 8%.
- 86% showed reduction in skin hardening (fibrosis).
- 85% demonstrated increased ability to perform ADLs.
- 96% reported being "very satisfied" or "satisfied" with the Flexitouch system treatment.
- Patients reported a significant increase in ability to control their lymphedema, along with an increase in function and a reduction of pain.
- Baseline limb volume and BMI were strong predictors of limb volume reduction — with limb volume a more important predictor of response. Thus, the most severely affected patients with lymphedema achieved the best treatment outcome.



RESULTS, CONTINUED

Sub-analysis of the data found no significant difference in limb volume reduction for bilateral patients treated twice daily versus those treated once daily on alternating limbs. Also, neither age nor cause of lymphedema was found to be a predictor of treatment-related limb volume reduction with the Flexitouch system.

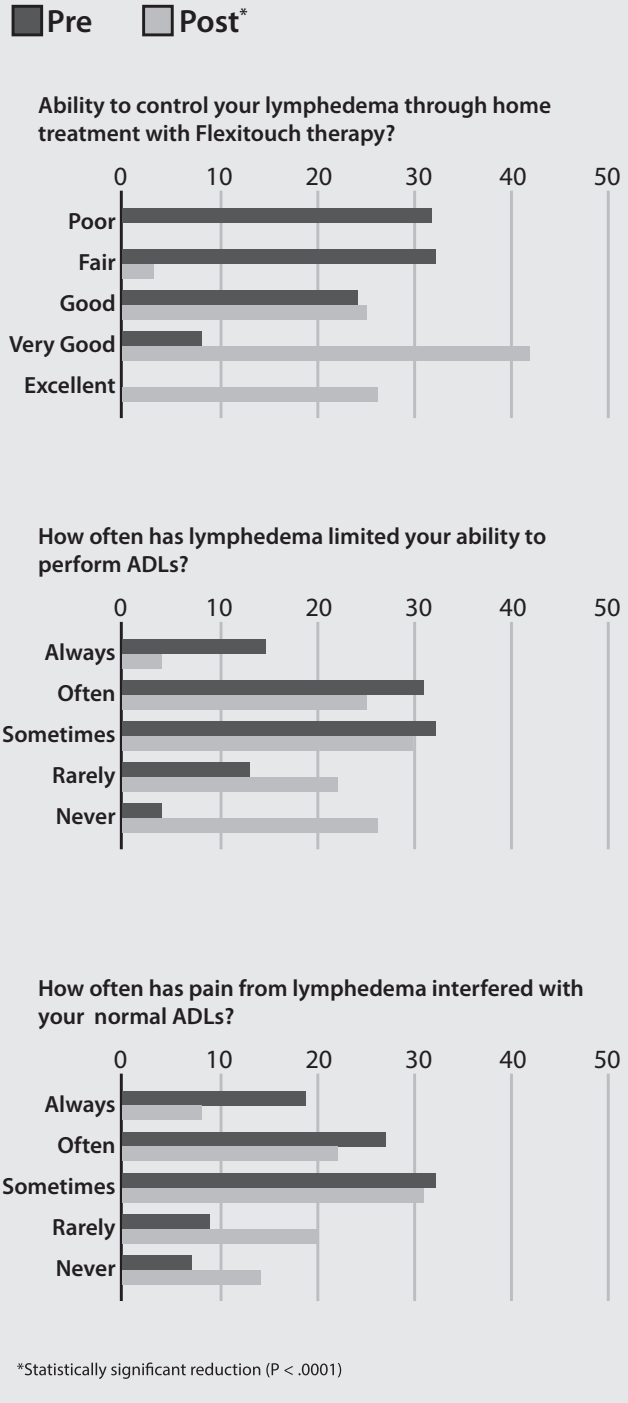
DISCUSSION

Limb volume reduction is an important objective goal of lymphedema therapy. Yet, beyond a volume decrease, the central clinical goal is to achieve significant improvements in patient-reported outcomes. This study demonstrates that home treatment with the Flexitouch system results both in a mean limb volume reduction of 8%, as well as a clinically meaningful set of real world benefits for the patient. These patients reported important improvements in function and pain, diminished tissue fibrosis, and an improved ability to perform activities of daily living (ADLs), and to enjoy freer active range of motion. These benefits are not achieved with all lymphedema therapies. It is important to note that limb volume reduction was measured after patients had already received conservative therapy and/or in-clinic CDT then subsequently used the Flexitouch system to self-manage at home for approximately 60 days.

CLINICAL IMPLICATIONS

The study provides confidence that the Flexitouch system can positively influence treatment outcomes for patients with lower extremity lymphedema. The data reflect a "real world" experience, where other treatment components were not standardized, and which showed statistically significant and clinically meaningful response to Flexitouch system treatment in a large cohort.

Pre- and Post-Flexitouch Treatment Patient-Reported Outcomes



*Statistically significant reduction (P < .0001)

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