Flexitouch® System Improves Quality of Life and Reduces Cellulitis in Lower-Extremity Lymphedema Patients

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INTRODUCTION

Lymphedema is a debilitating, chronic disease with significant negative effects on patient health and quality of life (QoL). Primary lymphedema occurs in 1 in every 6,000 live births in the U.S. Secondary lymphedema is the most common etiology of lymphedema in the U.S. and abroad with over 90 million people affected, most commonly by trauma to the lymphatic system due to surgery, obesity, radiation therapy and chronic venous insufficiency (CVI). While numerous studies demonstrate the efficacy of pneumatic compression, few tie these outcomes to patient QoL in lower-extremity lymphedema patients.

OBJECTIVE

The primary objective of this study was to demonstrate improved QoL of lower extremity lymphedema patients after use of the Flexitouch system, an advanced pneumatic compression device. The secondary objective of this study was to examine the reduction of cellulitis infections and determine the incidence of CVI in lymphedema patients.

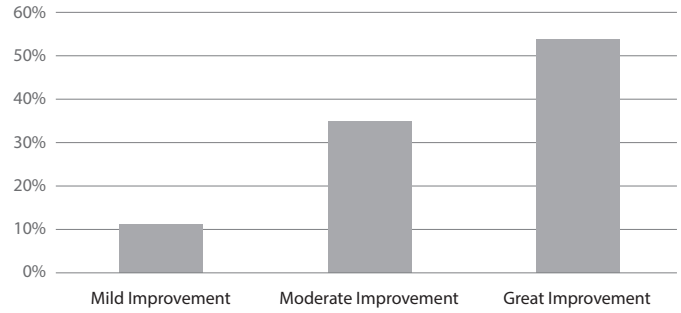
METHODS

A prospective study of 100 consecutive patients presenting treatment of lower-extremity lymphedema who met inclusion criteria was conducted between March 2011 and September 2014. Patients received the Flexitouch system in addition to standard lymphedema care (compression, local skin care and treatment of infection). Pre and post Flexitouch treatment data were collected on the number of cellulitis episodes, presence of venous insufficiency, number of ulcers, and limb girth. A self-reported QoL questionnaire was also collected pre and post Flexitouch system use.

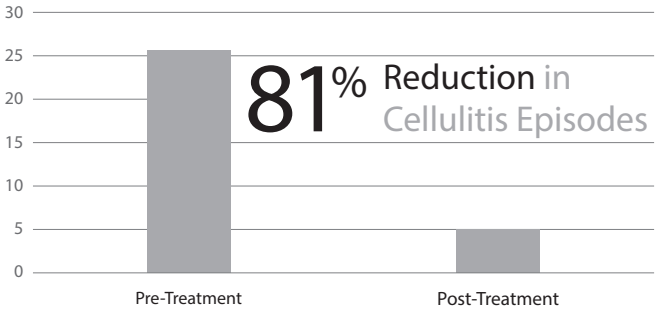
RESULTS

- The Flexitouch system was used 5.3 times per week by patients for an average of 12.7 months
- All patients reported overall improvements in QoL and lymphedema symptoms
  - 54% greatly improved
  - 35% moderately improved
  - 11% mildly improved
- 90% reported they would recommend the Flexitouch system to other patients
- Cellulitis episodes decreased by 81% (from 26 to 5, $P = 0.002$) following Flexitouch system use
- The number of ulcers decreased by 71% (from 7 to 2, $P = 0.007$) following Flexitouch system use
- Limb and calf girth decreased significantly following Flexitouch system use

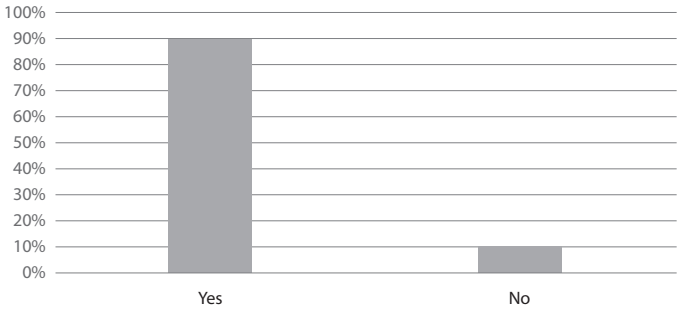
Symptom Control with Flexitouch System
(Avg. Treatment = 12.7 Months)



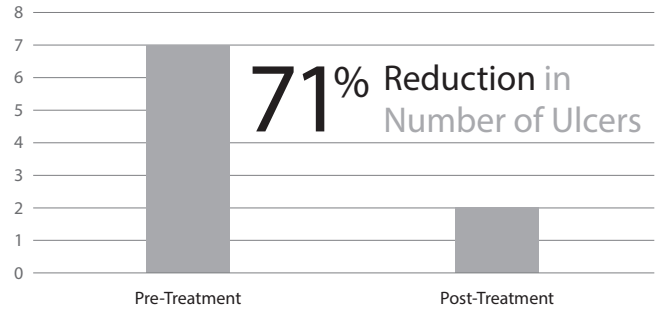
Reduction in Cellulitis Episodes after Flexitouch System Use
(Avg. Treatment = 12.7 Months)



Willingness to Recommend Flexitouch System to Other Patients



Reduction in Skin Ulcers after Flexitouch System Use
(Avg. Treatment = 12.7 Months)



DISCUSSION

This study was one of the largest to date to show the role that the Flexitouch system can have on improving QoL in lower-extremity lymphedema patients. The Flexitouch system also demonstrated the ability to decrease limb girth and reduce incidence of infection and ulceration. Reducing adverse events and improving patient health with the Flexitouch may help reduce health resource utilization and treatment costs for Flexitouch system patients. Despite the commitment to multiple treatment sessions per week, 90% of patients would recommend use of the Flexitouch system to other patients.

CONCLUSION

This study demonstrates that the Flexitouch is a well-tolerated lymphedema therapy that can help decrease limb girth while reducing complications such as infection and ulcerations in a manner that is well tolerated by patients.

This was an investigator initiated trial that was not sponsored by Tactile Medical.

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