A Preference Study of Basic Pneumatic Compression Devices

Authors: Matthew Rapcan, BS[1], Rosemary Sundin, BS[2], Emily Schueller, BEd[3]

BACKGROUND

Complete decongestive therapy (CDT) is the standard of care for patients who have been diagnosed with lymphedema.[1,2] Typically performed in a clinical setting, the aim of CDT, which includes manual lymphatic drainage (MLD), compression, exercise, and skincare, is to manage edema and prevent progression.[3] MLD is beneficial in directing excess fluid away from an impaired lymphatic region, but this care commonly relies on the use of trained health care providers in a clinic. Furthermore, MLD care can be limited by insurance, where the number of approved visits varies by payor. When CDT in the clinical setting has ceased, patients are expected to conduct a lifelong program of self-management at home.

Pneumatic compression devices (PCDs) are one such tool for self-management which help patients maintain the benefits of MLD from home. The first examples of PCDs for lymphedema management were introduced commercially in the 1950s.[4]

Since that time, this class of device-assisted therapy has evolved markedly to enhance therapeutic effectiveness and patient compliance. Consistent treatment compliance is paramount in managing the symptom burden of lymphedema.[5] Research has shown a strong positive association exists between a patient's perceived experience with their prescribed therapy and therapeutic outcomes; high satisfaction is a correlate of high treatment compliance.[6]

Several manufacturers have developed basic PCDs for lower-extremity lymphedema that allow patients to self-manage their condition from home. These basic PCDs include the LV Base from BioTAB Healthcare, the PCD-51™ from Lympha Press,® and Nimbl™ from Tactile Medical.® Each device consists of a controller that is attached, via hoses, to wearable leg garments that inflate with air and deflate. The garments from BioTAB and Lympha Press each have 4 chambers.

In contrast, each Nimbl leg garment utilizes eight chambers designed to offer more targeted pressure during treatment. When compared to the preexisting basic PCD from Tactile Medical, Entre® Plus, the Nimbl controller is 40% smaller, weighs under 2 lbs., with hose length reduced by 94% for lower extremity garments. Unlike the PCDs from BioTAB and Lympha Press, the Nimbl system has Bluetooth® connectivity to a mobile application, Kylee,™ that contains resources to help patients understand their condition, track their treatments, and how to share treatment progress results with their healthcare team.[7] Additionally, of the three devices, Nimbl is the only device to offer an optional battery pack allowing the user to untether from a power outlet while conducting treatment.

Patient and provider feedback are important for guiding innovations in PCD design. PCD users request a modern, consumer-friendly system that is simplified, easy to use, and compact. A PCD that is designed to meet the needs and lifestyles of lymphedema patients, without sacrificing efficacy, can be expected to improve treatment satisfaction and, consequently, compliance.

METHODS

This randomized study, comparing popular and commercially available basic PCDs (HCPCS billing code E0651) for lower extremity, was developed to assess treatment satisfaction, perceived efficacy, and establish the most important PCD user-experience attributes among prospective product users. This trial, conducted by an independent market research firm (Orman Guidance, Inc. – Edina, MN), utilized the LV Base from BioTAB Healthcare, the PCD-51 from Lympha Press, and Nimbl from Tactile Medical. Garment sizes for each PCD were chosen to be applicable for the widest range of potential lymphedema patients. Study subjects were asked a wide range of questions to describe and rate the PCD treatments they experienced. Among the several user-experience categories, subjects evaluated comfort, ease of use, portability, and perceived ability to maintain daily compliance and predict the device treatment experience from home.

Study participants were recruited using the market research firm's proprietary databases and included males and females, ages 55 to 70, BMI 25 to 40, with no history of lymphedema or prior PCD use. Study participants were blinded to the sponsor of the study, but not blinded to the brand or name of the devices used. This study was not conducted under IRB oversight, but participants provided written and verbal consent to have audio recorded during their interview.

All participants in this study experienced full-leg treatment with 2 PCDs. All subjects experienced treatment with Nimbl and were randomized to experience treatment from either Lympha Press or BioTAB, in a 1:2 ratio. Subjects were also randomized to which leg the Nimbl and the randomized device garments were worn during the interview, one device garment per leg for each subject.

31 subjects participated in the study: 23 women and 8 men. Each subject completed a single, 45-minute interview, which consisted of 15 minutes of treatment with the first device and 15 minutes of treatment with the second device with

user-experience questions asked before, during, and following each treatment. All subjects were instructed to wear socks and comfortable, loose-fitting clothing. Once PCD garments were donned, treatment was performed per the respective device user guides, with subjects seated, reclined, and their legs elevated. Following treatment with Nimbl and the randomized PCD, subjects were educated about lymphedema and how the devices are intended to treat the disease. The standard PCD treatment times were shortened for interviews to avoid respondent fatigue. Subjects 1 to 15, experienced treatment with the PCD controllers and garments one at a time, starting with the left leg, then the right. During the interview process, investigators identified patterns in the data that suggested the presence of primacy bias in subjects' responses. The interview methodology was adjusted for the last 16 subjects to have simultaneous treatment, one PCD garment per leg, to minimize any response bias.

Due to time constraints caused by the varying length of some of subjects' responses, not all subjects were asked the same questions from the prepared interviewer script. Additionally, because not all subjects were asked questions equally, and with each subject experiencing Nimbl plus only one other PCD, the number of responses varied across the dataset.

RESULTS

Combined Treatment Experience

The majority of subjects selected Nimbl as their preferred device for ease of use, perceived treatment compliance, and compactness, as highlighted in **Table 1**. When asked to describe the Nimbl controller, 95% (19/20) of respondents felt it was the most modern, 92% (12/13) said it was the easiest to handle, and 86% (19/22) reported it was the most state-of-the-art.

Following the use of their respective PCDs, subjects were asked to evaluate their treatment experience, including comfort level and satisfaction, with the responses detailed in **Figure 1**. 80% (4/5) of subjects selected Nimbl as the device that they felt provided the best sensation while undergoing treatment. The majority of respondents also selected Nimbl as the device that provided the most comfortable experience during treatment, as well as the device they perceived would be the easiest to use daily. 86% (6/7) of respondents reported that Nimbl offered the most perceptible benefit to manage lymphedema.

Subjects widely preferred the compression sensory experience during Nimbl treatment. Subjects described treatment as having a light massage that moved from the foot upward in a subtle manner, with 70% (16/23) of Nimbl respondents describing it as pleasant.

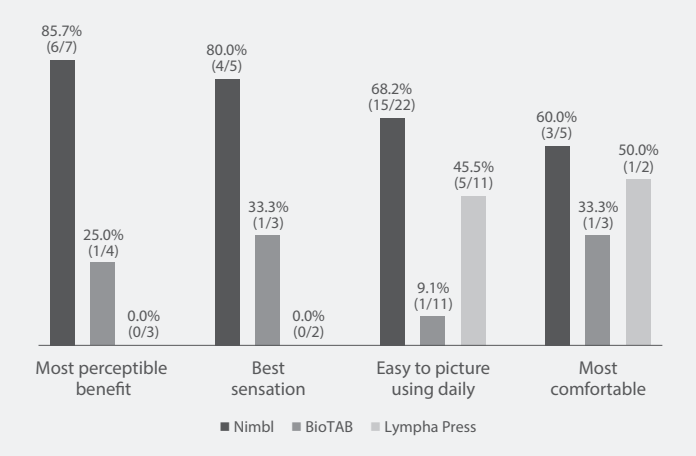
In other treatment experience categories, 71% (10/14) of respondents believed the Nimbl connectors, from the garment to the controller, were easy to handle. Participants commented that the large buttons and audible "click" when inserting the connector were beneficial. 89% (24/27) of respondents found Nimbl to have the most appropriate overall size, and 72% (21/29) selected Nimbl as the device they would want to have in their home.

Table 1: Treatment Experiences for Ease of Use, Compliance, Compactness, and Innovative Design

Category	Results*
Ease of use	▪ 92% (12/13) chose Nimbl as the **easiest to handle** controller. ▪ 82% (23/28) chose Nimbl as the device they perceive would be the **best fit for their lifestyle**. ▪ 82% (18/22) said Nimbl would be the **easiest to use controller with limited manual dexterity**.
Treatment compliance	▪ 85% (23/27) said Nimbl would be the device that would be **easiest to use wherever they are**. ▪ 83% (25/30) chose Nimbl as the device they would **take with when traveling**. ▪ 66% (19/29) chose Nimbl as the device they would **use at least once every day**.
Compact	▪ 88% (21/24) chose Nimbl as the device with the **most compact controller**. ▪ 85% (22/26) chose Nimbl as the device with the **most portable controller**.
Compact	▪ 95% (19/20) chose Nimbl as the device with the **most modern controller**. ▪ 86% (19/22) chose Nimbl as the device with the **most state-of-the-art** controller.

*Responses of subjects following treatment, when asked to evaluate the devices they experienced.

Figure 1: Treatment Experience Categories and Responses Following Nimbl, BioTAB, and Lympha Press Use**



**Percentages were calculated based on the number of subjects who felt that each device accurately represented the treatment experience category, when asked. Please note, not all study subjects were asked about each treatment experience category equally, and all subjects received Nimbl treatment, while approximately half of the subjects used BioTAB and Lympha Press, respectively.

Preferred PCD User-experience Attributes

Independent of their PCD treatments, subjects were asked to choose from a selection of terms and phrases to develop a ranking of the most important user-experience attributes a PCD should have. Detailed in **Table 2**, the subjects in this study were most interested in having garments and controllers that were easy to use and comfortable.

DISCUSSION

Management of chronic disease is predicated on compliance with prescribed therapy. In developed countries, compliance with long-term therapy averages only 50% for those with chronic illnesses.[8] Ensuring a positive patient experience during treatment is critical, as compliance with prescribed

Table 2: Top 3 Most Preferred PCD Attributes

Category	1st	2nd	3rd
Garment appearance	Easy to use	Intuitive	State-of-the-art
Touch and feel of garment	Comfortable	Lightweight	Soft
Controller appearance	Easy to see/ understand buttons	Easy to see/ understand connectors	Appropriate overall size
Touch and feel of controller	Easy to use on/off buttons	Easy to use connectors	Easy to handle
Ease of controller use	Easy to use	Uncomplicated	Easy to follow prompts

therapy has been shown to be highly correlated with patient satisfaction.[6] Lymphedema is a chronic disease with no known cure that, if left untreated, often leads to a reduced quality of life.[2] Among the difficulties associated with inadequate lymphedema management, patients can develop fibrofatty scarring, further damage to the lymphatics, increased inflammation, and hindered mobility.[2,9-12] For these reasons, it is important for lymphedema patients to have access to treatment that is both effective and a positive experience, to ensure consistent compliance in the management of their disease. As supported by the results in **Table 2**, having an overall user-friendly treatment experience is what these study subjects value most. Nimbl's innovative design was rated highly for its user-friendliness, as reflected in the responses of subjects. Nimbl was selected by the majority as the easiest to handle, easiest to use with limited manual dexterity, easiest to use wherever they are, the device they would take with when traveling, and device they would use at least once every day.

Based on the feedback from these subjects, the Nimbl system will offer patients the most flexibility to consistently adhere to therapy. Subjects commented that the portability of Nimbl, along with the options to have a travel bag and rechargeable battery, would be beneficial to completing therapy in varied locations, either in or outside a user's home.

CONCLUSION

Preference research that investigates what PCD users value most, and what leads to the greatest treatment satisfaction, is important to ensure device design is meeting patient needs. Through product innovation, guided by the feedback of current and future users, long-term management of lymphedema can be possible. The relationship between patient satisfaction and compliance with long-term therapy should be considered by healthcare providers when discussing treatment options with patients.

The results of this study indicate the differentiating features found in the Nimbl device, which includes portability, ease of use, and innovative design choices like Bluetooth® connectivity, will likely contribute to increased user satisfaction and compliance to therapy, and should be considered for lymphedema patients.

About the authors:
[1]Tactile Medical, Minneapolis, MN, USA
[2,3]Orman Guidance, Inc., Edina, MN, USA

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Tactile Medical
3701 Wayzata Blvd, Suite 300
Minneapolis, MN 55416 USA

tactilemedical.com

Customer Care
Text or Call: 612.355.5100
Toll Free Phone: 833.3TACTILE (833.382.2845)
Fax: 612.355.5101 / Toll Free Fax: 866.435.3949
Email: customerservice@tactilemedical.com
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