Novel body-weight device for compression garment donning in lymphoedema treatment

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Key words

Assistive device, compression garment, donning, lymphoedema

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Abstract

Background: Lymphoedema is commonly treated using complex decongestive therapy followed by the application of compression garments. These elastic garments are often difficult to pull over the enlarged limb. **Aim:** To design and build a novel device to assist with the donning of compression garments in a clinic and assess its use in practice. **Method:** The new device employs gravitational force and lower body strength to don compression garments. Device testing and design optimisation were performed at the university prior to conducting a preliminary clinical study. Patients evaluated three conditions to determine how well the new device performed against medi butler (medi), an existing commercial product, and using no assistive device. **Results:** The time needed to don the garment was longer when the devices were used in comparison to not using a device. No statistical difference was found in the ease of use of the body weight device versus the medi butler, however individual patients showed preferences towards different devices. **Conclusions:** The new device was found not to be effective for everyone. For patients who preferred to use an assistive device, however, the body weight device was preferred over the existing commercial product.

Lymphoedema is a medical condition caused by an excess of protein-rich fluid collecting in the subcutaneous tissue (Zuther, 2013; Brailsford, 2015). When the lymphatic system is functioning normally, the interstitial fluid passes into the lymphatic capillaries, through the lymphatic collectors, and returns to the circulatory system (Guyton and Hall, 2006; Greene et al, 2015). The system can be disrupted due to traumatic injuries, congenital reasons, surgery or radiation therapy associated with cancer treatment, resulting in an inability to properly drain the fluid (Rockson, 2001). This collection of fluid leads to swelling of the affected area, usually the legs or arms (*Figure 1*).

There are two types of lymphoedema: primary and secondary. Primary lymphoedema is caused by a developmental abnormality of the lymphatic system and has a lower incidence rate of 1.15/100,000 (Williams et al, 2005). Secondary lymphoedema occurs when the lymph nodes and collectors have been damaged by traumatic injury, surgically removed or radiated as part of cancer treatment (Shaw, 2014). It has been estimated that there are 140 million–250 million cases of lymphoedema worldwide (Zuther, 2013). There are roughly 2 million–3 million cases of secondary lymphoedema in the United States (Rockson and Rivera, 2008; Cormier et al, 2010), with prevalence rates of between 1.33 and 1.44 per 1,000 reported (Rockson and Rivera, 2008; Williams et al, 2005).

Lymphatic and circulatory system interactions

In order to better understand the function of the lymphatic system it is necessary to consider how it interacts with the circulatory system. The heart produces a pressure gradient within the arteries that delivers blood throughout the body. As blood reaches the capillaries, hydrostatic pressure forces fluid through the capillary walls and into the interstitial region surrounding the cells (Guyton and Hall, 2006; Goodman and Fuller, 2015). The capillary walls are semi-permeable and a protein-rich fluid is left within the capillaries, increasing osmotic pressure. As the fluid moves through the capillary beds and reaches the venous side, the hydrostatic pressure drops. This lower hydrostatic pressure means that the high osmotic pressure is able to draw about 90% of the fluid back into the circulatory system (Goodman and Fuller, 2015). The remaining 10% is returned through the lymphatic system. The lymphatic system is not pressurised like the circulatory system. Fluid is drawn into lymphatic vessels with the direction of flow controlled by one-way valves (Kerchner et al, 2008). Muscular contractions (lymphangiomotoricity) create localised pressure within regions of the vessels, causing fluid to flow in the direction allowed by the valves. Small vessels lead to larger vessels, eventually emptying into the venous system at the junction of the internal jugular and subclavian vein (Guyton and Hall, 2006; Cohen et al, 2001).

Lymphoedema results from an increase in protein levels within the intracellular fluid.

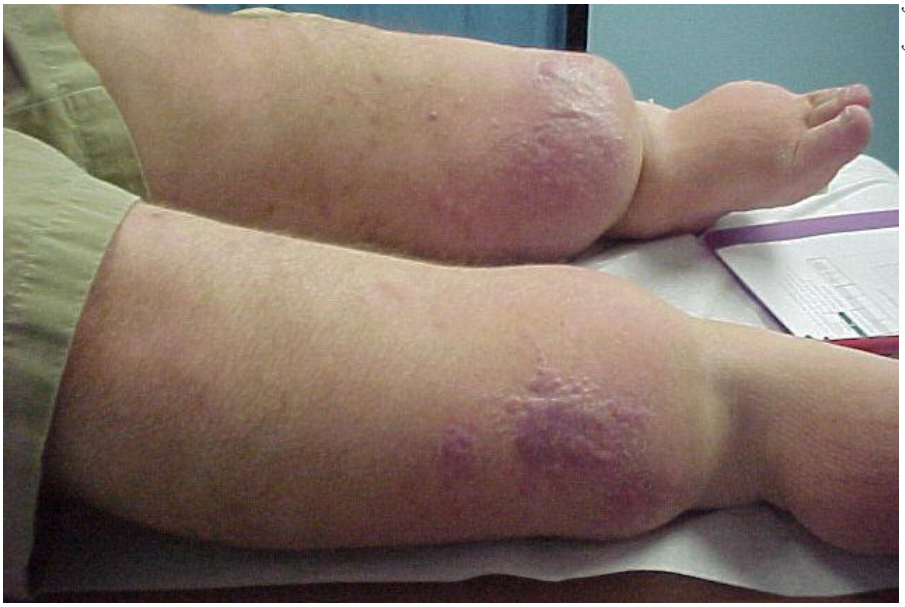
This reduces the osmotic pressure gradient across the venous capillaries, resulting in lower reabsorption of circulatory fluid. As the intracellular fluid collects, the protein levels are diluted and a new equilibrium condition is reached with a high intracellular fluid level.

Managing lymphoedema: garments and devices

Lymphoedema is an incurable disorder that can be best controlled through complex decongestive therapy (Ko et al, 1998; Cheville et al, 2014; Greene et al, 2015). Once the limb fluid volume has been reduced through therapy, compression is used to minimise the influx of fluid. A common way to achieve compression is to use specially-designed garments or stockings (Brennan and Miller, 1998). Often the existence of secondary lymphoedema goes unnoticed because these garments are worn under clothing (Thomas and Hamilton, 2014).

Compression garments typically provide approximately 30–60 mmHg of external pressure to the affected limb (Brennan and Miller, 1998). Achieving this level of pressure requires a relatively thick garment with high elastic force similar to a wetsuit. For a leg garment, the compression level is highest at the ankle and decreases towards the heart (e.g. 100% at the ankle, 70% at the knee and 40% at the thigh). This results in a pressure gradient that helps to drive the fluid out of the limb. These garments can be quite difficult to put on (Brennan and Miller, 1998).

Currently, there are several devices on the market to help people don compression garments. These products range from anti-friction aids to rigid metal frames. The effectiveness of these products varies, but they all have one shortcoming: they require the user to pull the garment onto their limb using upper-body strength. Many patients, especially older people, have limited upper-body strength. As a result, they require the help of another person to assist them. In the case of an elderly couple, neither person may have sufficient strength to don the garment, thus the patient may require aid from another able person.



John Jordi

Figure 1. The legs and arms are most commonly affected by swelling related to lymphoedema.

This article describes the design and construction of a novel biomedical device to assist with compression garment donning and a preliminary clinical study to evaluate the effectiveness of the device when used by lymphoedema patients.

Method

Device design

The main focus of the new design was to overcome a major limitation of existing devices: the reliance on upper-body strength to force the compression garment over the leg. The new apparatus has been designed to employ the force of gravity and the strength of the lower body to help the person don the compression garment. This task has been accomplished using a foot pressure plate and a pulley-and-cable system (*Figure 2*). Core components of the device consist of a base, a pressure plate, an upper plate, four polished

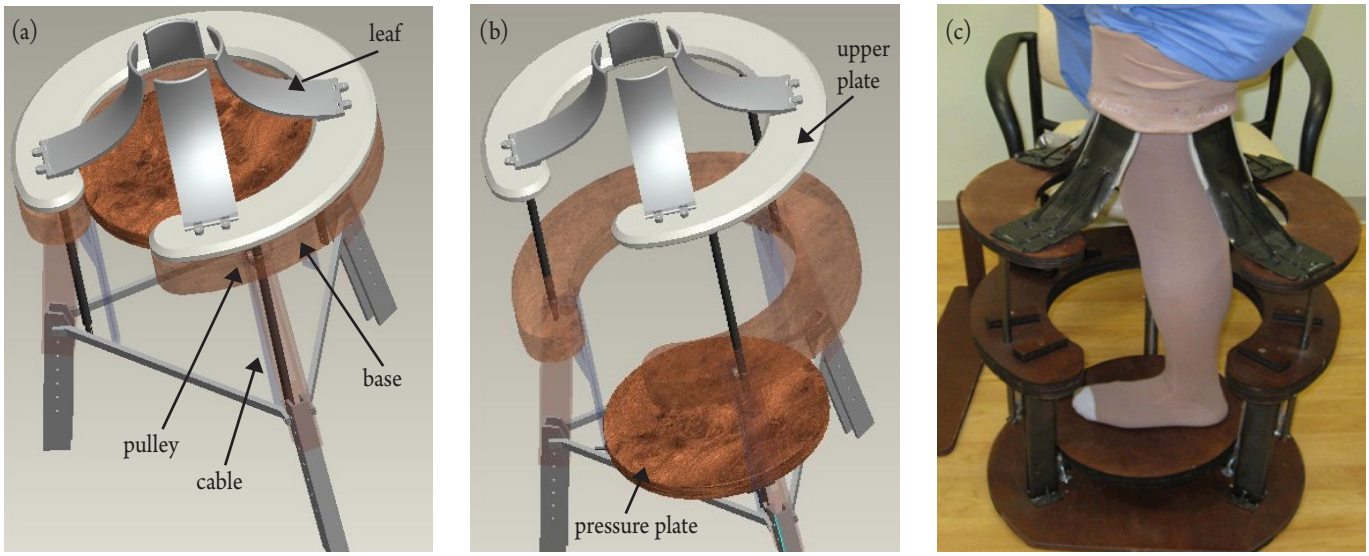


Figure 2. Three-dimensional computer-aided design model of the body weight device showing it a) in the contracted position and b) in the extended position. c) A patient using the body weight device to don a compression garment.

Table 1. Results for donning the garment and ease of use for each subject (n=9).

	Average donning time (sec)			Ease of use		
Subject	***None***	***BWD***	***MB***	***None***	***BWD***	***MB***
1	55	116	101	88.8%	46.1%	26.2%
2	84	145	140	46.8%	67.4%	58.6%
3	48	97	87	50.0%	9.8%	11.3%
4	47	85	62	38.4%	55.5%	44.9%
5	27	65	48	82.5%	40.5%	96.2%
6	53	95	104	95.3%	3.3%	19.8%
7	40	90	72	94.1%	68.2%	67.7%
8	71	136	189	80.0%	76.3%	15.4%
9	86	117	126	93.3%	50.9%	19.7%
Mean	57	105	103	74.0%	46.0%	40.0%
SD	20	26	44	23.0%	25.0%	29.0%

BWD=body weight device; MB=Medi-Butler; SD=standard deviation

aluminium leaves, three legs, three cables, and three pulleys. The leaves are attached with hinges to the upper plate. The hinges permit the leaves to open and follow the contours of the leg during donning. In addition, they also allow the apparatus to accommodate different leg sizes. During operation, the user positions the garment with the foot of the garment inside the leaves and the remainder draped around the outside (*Figure 2c*).

With the garment properly positioned on the apparatus, the user slips his/her foot through the opening and presses down until the foot is properly positioned in the heel. The user applies his/her body weight to the leg, pressing on the pressure plate and causing it to lower under the applied force. Simultaneously, the upper plate moves upwards because it is connected to the pressure plate with cables and pulleys.

This mechanism functions by connecting the pressure plate to rods attached to the upper plate using cables. As the pressure plate moves downward, it pulls the cable. The cable passes over a pulley, changing the direction of motion and causing the rod to move upwards. This system provides a 2:1 kinematic ratio, causing the garment to be applied at a rate of 2 cm for every 1 cm of leg travel. As the foot is lowered, the leaves slide the garment up the leg progressively. This mechanism is effective because the garment does not need to slide on the leg; it only needs to slide over the low-friction metal leaves.

The apparatus is designed to be circular, with an opening on one side to ease the ingress/egress of the leg. The approximate dimensions are as follows: a fully extended height of 99 cm, a fully collapsed height of 56 cm, a total travel distance of 70 cm, and an overall diameter of 50 cm. A prototype of the device was built and tested by generally healthy university students without lymphoedema. Minor modifications were made to the design to optimise device performance. These included the contour of the leaves, clearance hole diameters, adding a low-friction surface to the edge of the leaves (split Teflon tubing), and increasing the stiffness of the leaves with welded support rods. Following these optimisations, the device operated well on people without lymphoedema and was ready for a preliminary clinical evaluation.

Preliminary clinical evaluation

The performance of the device was evaluated through a preliminary clinical study at Siskin Hospital Lymphedema Clinic. Study participants were recruited from the patient population at the clinic. No gender bias or balancing was made in the study design due to the limited number of potential participants. The original enrolment consisted of nine female participants and two males. However, the two males originally enrolled were unable to use the device due to a sharp transition in leg geometry at the knee, causing discomfort. As a result, the final list of participants enrolled in the study consisted of nine females.

The test protocol and informed consent form were approved by the institutional review boards at both Western Carolina University and Siskin Hospital. All participants were patients at Siskin Hospital Lymphedema Clinic and signed the informed consent form prior to study participation.

The clinical portion of this research was conducted by the second author while employed as a certified lymphoedema therapist (CLT — Lymphology Association of North America) at the clinic. The study was designed to compare the effectiveness of using the new body-weight device (BWD) against an existing device, the Medi-Butler (MB), and using no device (except gloves when needed) when donning compression garments. Patients were given instructions on how to properly use each device and an opportunity to practice donning the garment until they felt they could effectively use them both. For the study, each patient used all three methods to don the garment, cycling between each method three times for a total of nine donning cycles. The order of testing was block randomised to counteract learning effects and the time required to don the garment using each method was measured.

Patients were asked to change into shorts and take off their compression garments prior to testing. A Perometer (400NT Pero-System, Messegräte GmbH, Wuppertal, Germany) was used to measure leg volume and the circumference of the affected leg or legs. A Perometer is an optoelectronic device that scans the limb and automatically calculates the limb volume (Stanton et al, 1997; Badger et al, 2000).

Following the nine donning cycles, a visual analogue scale (VAS) was used to assess the perceived difficulty of donning the garment using each device. A VAS is an effective way to obtain continuous quantitative data for a subjective parameter (Bijur et al, 2001; Gallagher et al, 2002; Hayes et al, 2013). A line of specified length is presented to the patient, who uses a pen to mark his/her score. The distance from one end of the scale is measured and divided by the overall distance to obtain a value between zero and one. These data can be evaluated using standard statistical methods often applied to continuous quantitative data.

Statistical analysis

A repeated measure one-way analysis of variance was used to compare the differences in values between donning time and the ease of use. Bonferroni corrections were applied and post-hoc analysis performed to find differences between individual devices. Significance was set at α=0.05 for all analyses.

Results

Significant differences were found (p<0.001) in the time required to don garments using

the different devices (*Table 1* and *Figure 3a*). Patients were able to don compression garments faster using no assistive device (57 sec) than the BWD (105 sec) or the MB (103 sec). Pairwise comparisons during post-hoc analysis showed a difference between no device and the BWD ($p<0.001$) as well as the MB ($p=0.005$). There were no differences in donning time observed between the BWD and the MB ($p=1.000$).

Similarly, patients found it easiest to don a compression garment using no device, with a score of 76% on the VAS (*Figure 3b*). This was followed by the BWD at 46% on the VAS, and the MB at 40% on the VAS. Patients reported no significant differences in the difficulty of using each device ($p=0.081$). Post-hoc analysis showed no difference between using no device and BWD ($p=0.133$), no device and MB ($p=0.074$), and between the two devices ($p=1.000$).

The ease of use data were also used to determine user preference (*Figure 3c*). Seven of the nine patients (78%) found it easier to don the compression garment using no device compared to the BWD (*Table 2*). Seven patients found it easier to don the compression garment using the BWD versus the MB. Six patients (67%) found it easier to don the compression garment using no device compared to the MB.

Discussion

Although no significant differences were found between the BWD and the MB, three times as many people found the BWD easier to use than the MB. These results are not statistically significant, possibly due to the low number of study participants. Another consideration that should be taken into account is that some devices work better for some people than others. Even if a large population trial shows the BWD to clearly outperform the MB or vice versa, there may still be patients who prefer one device over the other. Due to the significant differences in the devices, there may be market potential for both.

In this study, the fastest and easiest way of donning compression garments was found to be no device at all. However, this may be due to the patient population selected. Clearly, there is a need for compression garment-donning devices for many people. A follow-up study with a larger patient population and an inclusion criterion specifying that the patient uses an assistive device to don compression garments may yield more focused results.

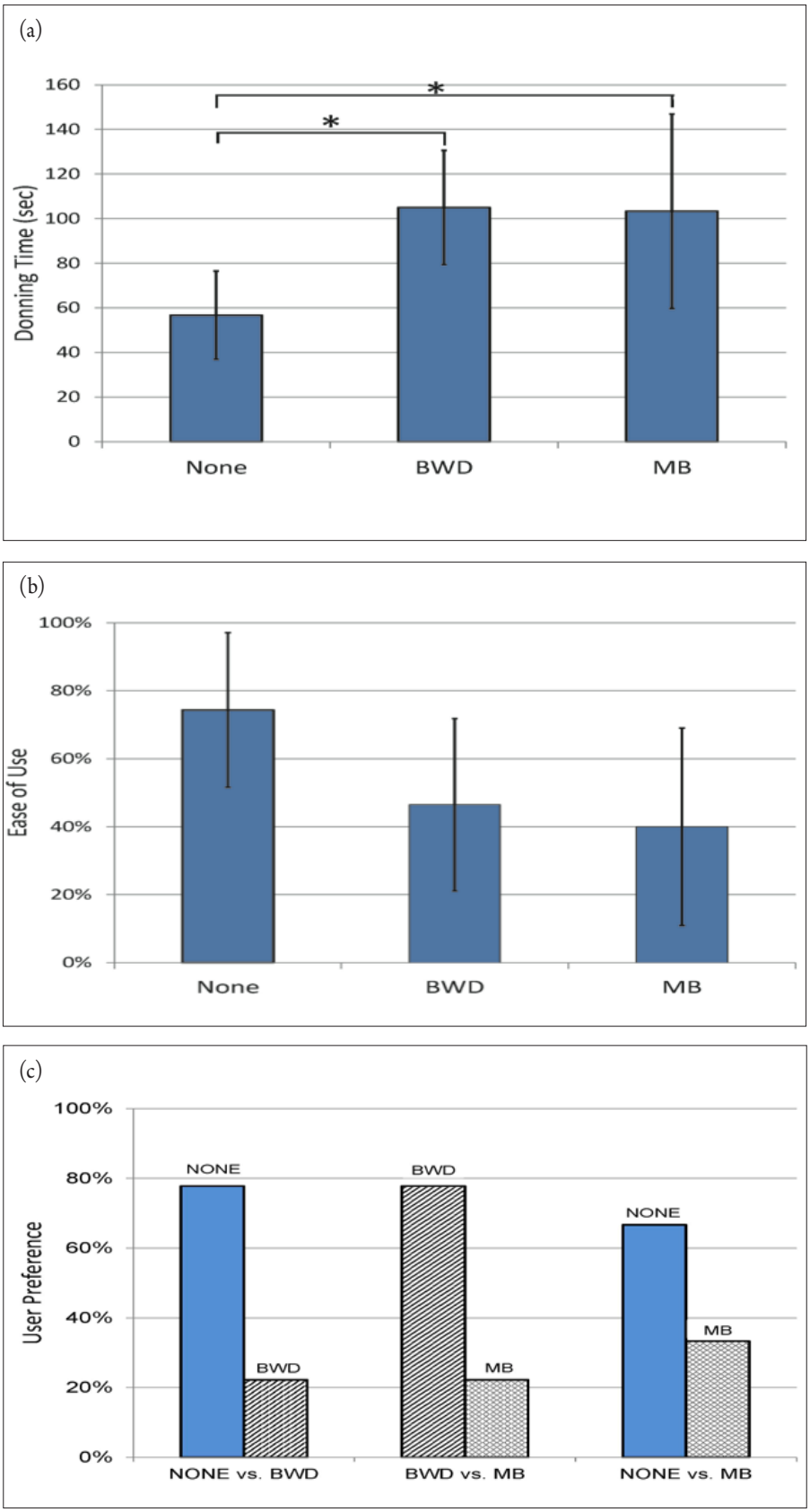


Figure 3. (a) Time needed to don a compression garment using no assistive device (none), the body weight device (BWD), and the Medi-Butler (MB). (b) The ease of use measured as a percentage of the entire range of the visual analogue scale (100% being the easiest) for no device, the BWD and MB. (c) Percentage of patients who preferred one device over another in side-by-side comparisons of no device, BWD and MB.

Table 2. User preference between each device from 'ease of use' data.

	Average donning time (sec)		
Subject	*None vs BWD*	*BWD vs MB*	*None vs MB*
1	1	2	1
2	2	2	3
3	1	3	1
4	2	2	3
5	1	3	3
6	1	2	1
7	1	2	1
8	1	2	1
9	1	2	1

Preference: None = 1; BWD = 2; MB = 3

BWD = body weight device; MB = Medi-Butler

Limitations

There are several limitations of this study and care should be taken when interpreting the results. The study was limited in number of subjects. This may have contributed to the lack of statistical significance observed in the data. In addition, the study only included females. This may have been a result of a lack of males willing to participate in the study or make-up of the patient population who had scheduled clinic visits on the days when the study was performed. Several males were asked and the two that did participate were not able to complete the task as the leaves were too tight for comfort on their leg — they had significant swelling and change of size from knee to thigh.

The current version of the device may be ill-suited for use by males, as both males who were going to participate found that the garment on the device caused pain and binding at the knee transition. Each opted out due to the pain/discomfort and not wanting to hurt himself. The contour of the leaves has an effect on how the device slides up the leg. The current shape of the device is a gradual curve that pushes the compression garment open at the tip of the leaves as the leg is pushed through (*Figure 4a*). Sharp transitions in leg geometry may cause the leaf to bind, making the device ineffective (*Figure 4b*). Changing the leaf design may correct this problem (*Figure 4c*). However, this may create problems for the patients who find the current leaf design effective. If this is the case, it may be necessary to have a custom leaf design based on individual patient leg geometry.

Possible future development

This device was designed to apply compression garments to the lower limbs. A similar device could be designed to use the weight of the upper body to apply compression garments to the arms. Although the body weight would not be as easily applied through the arms because people do not generally use their arms to support the body, significant force could easily be applied through pushing. It should be noted that other assistive devices, such as the MB, which require two hands to properly pull the device, cannot be used to apply compression garments to the arm.

Conclusions

The BWD has the potential to improve how compression garments are applied to the lower limbs in the treatment and long-term management of lymphoedema. Although statistical data were limited due to low patient numbers, most patients who preferred to use an assistive device over no device at all preferred to use the BWD over the existing commercially-available product evaluated. Therefore, even though the device was not shown to be effective for all users, it may be helpful to some people who meet the qualifying conditions. Future work will include further design optimisations based upon feedback from the preliminary clinical study and the planning of a larger-scale and more focused clinical study.

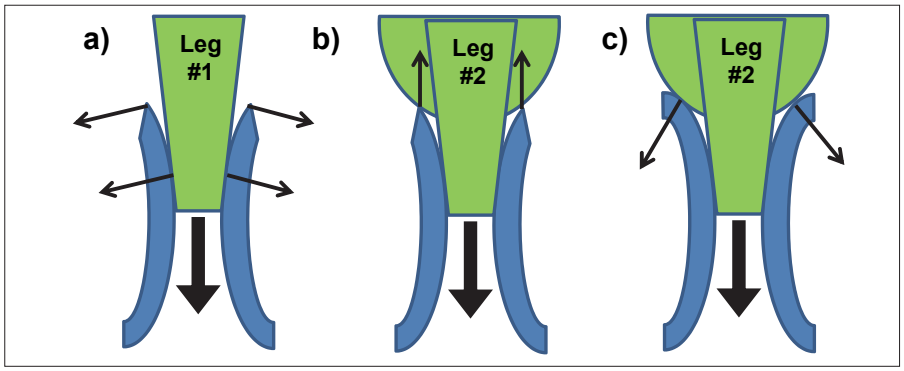


Figure 4. (a) The original leaf contour was effective for legs with gradual contours. (b) Legs with sharp transitions do not allow the spreading force to be applied at the correct location of the leaf, causing the leaf tip to apply force directly to the leg, stopping movement. (c) A larger contour would redirect the force to allow proper leaf spreading.

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