From the American Venous Forum

Journal of Vascular Surgery
Venous and Lymphatic Disorders™

Variability in leg compression provided by gradient commercial stockings

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Background: **Compression stockings are commonly prescribed by physicians for lower extremity edema and venous insufficiency. However, no data are available for clinicians to assess the relative quality of various brands, particularly low-cost generics now available directly to consumers through the Internet. We examined the actual compression provided by gradient stockings from multiple manufacturers.**
Methods: **A total of 36 class 2 (20-30 mm Hg) men's medium-sized below-knee compression stockings from six different manufacturers (n = 6 of each brand) with approximately the same quality and materials were chosen to be studied. Identifying brand names were removed, and they were randomly and blindly tested by a technician in accordance with accepted industry standards. A calibrated constant rate of extension tensile instrument (Zwick Z010; Zwick Roell, Ulm, Germany) was used, and the tension generated by the stockings at the ankle and calf was measured using minimum, average, and maximum circumference sizes. All measurements were performed in duplicate.**
Results: **The compression pressures generated by the stockings were almost all within the stated range of 20 to 30 mm Hg at the ankle, but all except one were below 20 mm Hg at the calf. There were also significant differences between manufacturers at both the ankle and the calf ($P < .0001$). The expected pressure reduction between the two locations varied, but one stocking had only a minimal 2 mm Hg (8%) gradient, which was significantly less than all of the other tested brands and below the recommended 20% to 50% reduction. Cost analysis demonstrated that the discount brands were significantly lower in price but provided absolute compression and pressure gradients similar to those of the more expensive brands.**
Conclusions: **There is significant variability among stockings, both in the absolute pressures and in the pressure gradients generated from the ankle to the calf, thought to be functionally important for venous flow. The cheaper stockings offered the same degree of compression and pressure gradient as the more expensive brands. These results suggest the need for manufacturing standards in the United States and a revision in labeling requirements to mandate more accurate and complete pressure disclosures. (J Vasc Surg: Venous and Lym Dis 2015;3:431-7.)**

Clinical Relevance: **The clinical spectrum of venous insufficiency varies widely from minor cosmetic concerns to severe and recalcitrant venous ulcerations. The main treatment of chronic venous insufficiency is the use of compression stockings. Little is known about pressures actually generated by ready-to-wear compression stockings prescribed to patients. This study was initiated with the goal of at least partially addressing this deficiency and examining the variability of compression pressures generated by commercially available ready-to-wear medical stockings from a variety of manufacturers. Such information would help physicians in recommending the optimal stockings for their patients.**

The clinical spectrum of venous insufficiency varies widely from minor cosmetic concerns to severe and recalcitrant venous ulcerations. The incidence of venous insufficiency increases with age and is more common in women.[1] It has been estimated that approximately 25 million people in the United States suffer from venous reflux disease, with about 500,000 to 600,000 of these having venous ulcers.[2] It has further been suggested that 1% of all adults will develop a venous leg ulcer at some point in their lives.[3] With such a high prevalence and consequently large number of people affected, leg ulcers alone represent a significant economic burden on the health care system, approximately $1.5 billion to $3 billion annually.[4] The mainstay of the medical treatment of chronic venous insufficiency, be it varicose veins or venous ulcers, is the use of compression stockings. The effectiveness of compression therapy, particularly for the treatment of ulcers, correlates with the amount of pressure generated, with high pressures generally required for severe venous disease.[3,4]

Whereas compression therapy has been shown to improve healing rates in patients with venous ulcers, comparatively little is known about pressures actually generated by ready-to-wear compression stockings prescribed to patients.[5] Lurie and Kistner[6] recently reported variable in vivo interface pressure readings in up to 11% of commercial stockings, with >5 mm Hg difference in

From the Department of Surgery, University of Oklahoma College of Medicine.
This study was supported by a 2014 grant from the American Venous Forum and the BSN-Jobst Research Award (H.M.).
Author conflict of interest: none.
Presented at the Twenty-seventh Annual Meeting of the American Venous Forum, Palm Springs, Calif, February 25-27, 2015.
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The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.
2213-333X

http://dx.doi.org/10.1016/j.jvsv.2015.07.001

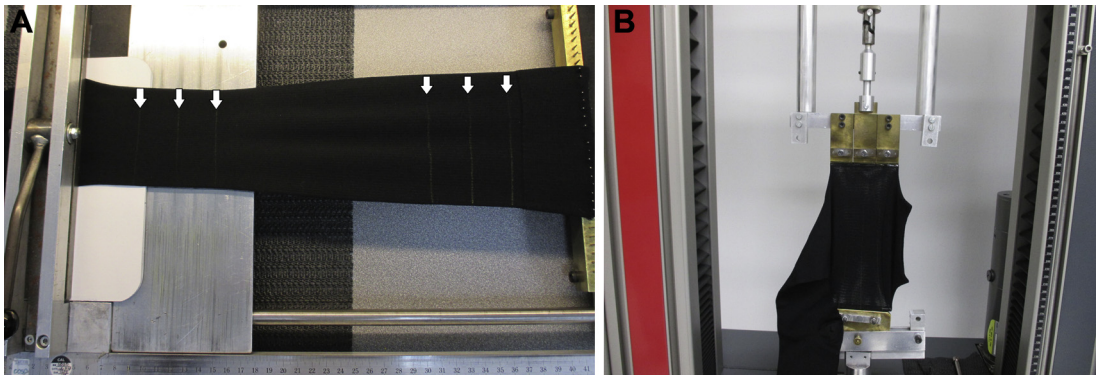

Fig 1. A, Stocking stretched and marked (*arrows*) for pin placement where the pressures will be measured. **B,** The Zwick Z010 tensile instrument performing a stretch cycle.

pressure than that specified by the manufacturer. This variability was sufficient in some cases to reclassify the stockings into a different grade of compression. The authors did not, however, report which brand of compression stockings did not fall within the advertised range of pressures. In addition to the initial compression provided by the stockings, the durability of such pressures is also not well characterized. Jünger et al demonstrated in a small series of 20 patients that the interface pressure was maintained during a period of 6 weeks.[4,7] However, most patients are instructed to use their stockings for 6 months before replacement, and this study was limited to one type of stocking and did not offer a comparison to other manufacturers.

The Food and Drug Administration classifies medical support stockings as a class II medical device with exemption from current good manufacturing regulations. As there are no U.S. manufacturing standards within this industry, different manufacturers are afforded flexibility in the design and quality of the finished product that is sold to patients. This suggests the possibility that there can be high variability in the compression pressures generated on the basis of the manufacturer, in particular those that offer direct products to patients at discounted prices. Furthermore, a recent Cochrane review on preventing recurrent venous leg ulcers concluded, "There is insufficient evidence to aid selection of different types, brands, or lengths of compression hosiery."[8] This study was initiated with the goal of at least partially addressing this deficiency and examining the variability of compression pressures generated by commercially available ready-to-wear medical stockings from a variety of manufacturers. Such information would help physicians in recommending the optimal stockings for their patients.

METHODS

Graduated compression stockings from six different manufacturers were selected for testing and were purchased from retail distributors unaware of this study. An effort was made to compare similar products from each manufacturer on the basis of content material and each manufacturer's assessment of equivalent competitive products. On this basis, each stocking was chosen to contain a minimum of 20% and a maximum of 30% spandex material. The stockings were all closed-toe below-the-knee medium-sized compression stockings for men, class 2 (20-30 mm Hg), and represented the company's basic brand of stocking. The brands included for testing were the major market leaders in the United States: A, BSN/Jobst (Charlotte, NC); B, Sigvaris (Peachtree City, Ga); C, Medi (Whitsett, NC); and E, Juzo (Cuyahoga Falls, Ohio). Two additional brands were selected that were readily available online directly to consumers: D, Second Skin/Truform (Cincinnati, Ohio); and F, Absolute Support Value Brand (Brooklyn, NY). After purchase, all identifying labels were removed or covered with an indelible marker to blind subsequent testing. Each stocking was randomly numbered (www.random.org/sequences) with indelible ink.

Before testing, the stockings were allowed to stabilize in the unstretched relaxed state at a temperature of 70° ± 2°F and a relative humidity of 65% ± 2% for a minimum of 24 hours. Measurement of the compression pressures for each stocking was performed at both the ankle and the calf. A constant rate of extension tensile instrument (Zwick Z010; Zwick Roell, Ulm, Germany) was used to measure the compression pressures at the manufacturer's predetermined minimum and maximum diameter for the stocking size. The instrument was calibrated according to industry standards as defined by the ASTM E4-99 guidelines.[9] The testing was performed by a professional tester with >10 years of experience in textile manufacturing and quality control. Each stocking was placed on a marking board with a longitudinal centerline and fastened at the heel with clamps. The stocking was then stretched longitudinally to a predetermined length of 43 cm and fastened at the upper end with pins (Fig 1, *A*). The areas at which compression pressures were to be measured were marked with perpendicular lines drawn 3 cm apart for pin placement. Once marked, the stocking was fastened to the constant rate of extension tensile instrument testing apparatus