NOVEL COMPRESSION GARMENT PROTOTYPE TO IMPROVE ADHERENCE IN SUBJECTS WHO CANNOT WEAR COMPRESSION

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INTRODUCTION

Chronic venous insufficiency (CVI) affects approximately one third of all adults in the United States. Patients suffer from lower extremity varicose veins, swelling, and pain. The condition may lead to the development of venous leg ulcers (VLU), which afflict around 1-2% of the population [1]. VLU are the most common type of chronic leg ulcers, accounting for more than 70% [1]. About half of VLU are chronic, tending to become malodorous, painful, and infected [2]. Compression of the lower extremities is the most effective therapy for CVI as well as primary and secondary prevention of VLU. While a number of compression garments and devices are widely available, most have significant disadvantages that limit patient adherence, such as cost, difficulty with application, and discomfort [3]. A new two-piece compression garment has recently been developed (CoolFlex™, Sigvaris USA), which aims to succeed on all fronts, combining appropriate compression with ease of use, comfort, temperature control, and aesthetic appeal. The purpose of this retrospective chart review is to evaluate the experiences of patients wearing the CoolFlex™ prototype.

MATERIAL AND METHODS

- The CoolFlex™ compression system is composed of two pieces (Figure 1):
  1. Transition liner: the inner layer consisting of a modified compression stocking with compression from toes to ankle only.
  2. CoolFlex™ compression wrap: the outer layer to be worn around the gaiter area, providing compression from ankle to knee.
- All products were donated by Sigvaris USA
- Patients with CVI in whom traditional methods of compression (i.e. stockings) were not practical were selected to try the CoolFlex™. Patients with active VLU were not considered for CoolFlex™ initiation.
- Various leg length and circumference measures were taken and used in conjunction with a sizing chart to outfit each patient with the appropriate size compression garments.
- Instruction and demonstration regarding proper use of the compression system was performed, and patients were observed donning the compression garments without any assistance.
- Data regarding patient experience after initiation of the CoolFlex™ garment were assessed via chart review.

RESULTS

- We reviewed the charts of 10 patients from which 80% (n=8) were male. The mean age was 58.1 years and most (60%) were white.
- Half of our cohort had previous VLU that had recently healed (within 2 weeks of CoolFlex™ initiation).
- Reasons for patients' inability to wear compression stockings included: limited dexterity, lack of physical strength, lack of flexibility, pain from use, and skin irritation.
- The average duration of CoolFlex™ use was 104 days.
- 100% of patients were still using the compression garment at the point of chart review.
- Nine (90%) patients reported that they were able to don the new garment without assistance, and that it was easier to use and more comfortable than the standard compression stocking. One patient reported never using compression stockings, and therefore these qualities could not be assessed.
- No adverse events were reported in 9 patients; however, one patient experienced minor skin irritation located directly under the hooks attached to the garment.
- All patients reported that leg swelling reduced considerably with use of the compression garment.
- 80% of patients reported no development of new ulcers during the period of use.

CONCLUSIONS

- The new CoolFlex™ compression garment appears comfortable and increases adherence in patients with CVI, while effectively managing edema.
- This garment is well-suited for all but particularly useful in patients not amenable to traditional modes of compression.
- Further comparative effectiveness trials are needed to confirm these promising results.

REFERENCES

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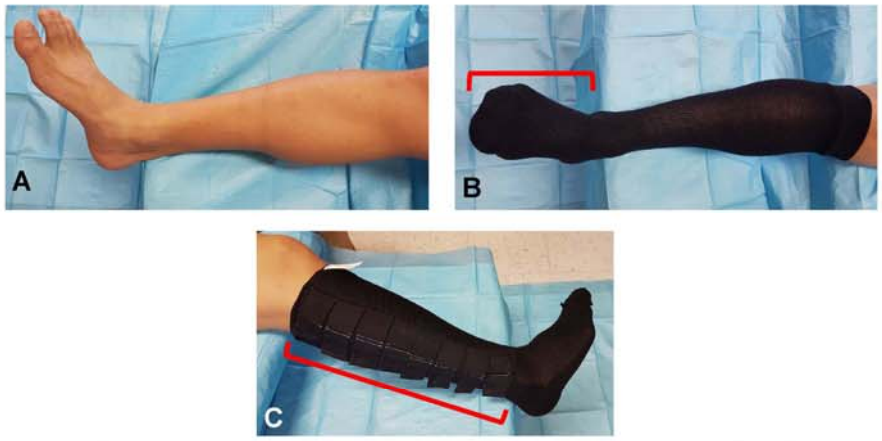

Figure 1. (A) Right lower extremity before placement of compression garment. **(B)** Placement of transition liner, a modified compression stocking that delivers compression from tip of the toes to the ankle (Red line). **(C)** Right leg after placement of compression garment. It delivers compression from the ankle to the knee. Each strap is hooked into the strong mesh that the covers the garment (Red line).