

Circulator Boot Efficacy and Effectiveness in Clinical Practice

THE CIRCULATOR BOOT™ has been used successfully for more than 25 years to produce healing in patients with chronic recalcitrant ulceration and related conditions due to vascular insufficiency in the feet. There is a growing number of clinicians actively using the technique as the first treatment of choice. An estimated 4,000 limbs have been saved and many lives saved. It has FDA listing in the USA and Health Canada listing in Canada.

Discussion

Documented evidence ^{1, 2, 3, 4, 5} shows that the Circulator Boot treatment method is effective as claimed. Its efficacy as a treatment modality — and its overall effectiveness in practical clinical settings along with appropriate wound care and infection control — has been conclusively established as follows:

1. When only one of the patient's legs is treated, the contra lateral leg serves as the control. It functions in the same environment as the treated leg, with the only difference being that the treated leg receives Circulator Boot therapy. It is well documented that the control leg deteriorates further while the treated leg improves.
2. Previous clinical experience shows that a low oxygen level in the tissues produces ulceration and prevents healing in all cases ⁴. Where the transcutaneous oxygen tension (tcPO₂) is below 20 mm Hg, healing is impossible with all other methods, but with the Circulator Boot most patients show successful outcomes.
3. Pneumatic pressure devices have been in use for at least 190 years to treat patients with poor circulation. During this time the equipment has been continually improved to make

use of new materials, more accurate sensors and better electronics. Clinicians have repeatedly refined the techniques to take advantage of medical advances such as antibiotics and topical oxygen. The healing process with the Circulator Boot is well characterized and understood. The central concept of using cardio-synchronous end-diastolic pneumatic compression to increase blood flow to the extremities is self-evident and logical.

4. Published literature gives a great deal of information on the biochemical nature of the healing process that fully supports the scientific basis of the Circulator Boot.
5. Detailed published data ^{3, 4, 5} is available that documents the clinical progress of patients who have received Circulator Boot treatment. These patients had typically received maximum attention using conventional wound care methods as first line therapy; yet their condition deteriorated. Upon commencement of Circulator Boot treatment, as the second line therapeutic modality, their condition quickly started to improve. Healing continued during treatment and after treatment.

Conclusion

It is concluded therefore that effectiveness is positively established with sufficient documented strength of evidence for its listed indications at a Quality of Evidence II-2 and a Classification of Recommendation A, using the ranking of the Canadian Task Force on Preventive Health Care. The Circulator Boot is recommended as appropriate and cost-effective for use as a therapeutic modality in treating lesions of the feet and legs where high clinical intensity is needed.

Recommendations

1. End-diastolic compression using the Circulator Boot should be recommended for patients presented with vascular insufficiency in the lower extremities.
2. Compression bandages, pressure off-loading, wound management therapy and physical exercise should be used.
3. Circulator Boot treatment should commence as soon as practicable when there is no healing response for 30 days or if there is evidence of infection or acute arterial thrombosis.
4. The Circulator Boot should be considered prior to any surgical procedures including angioplasty, resection and amputation.
5. After healing, patients should be instructed and encouraged to maintain adequate nutrition and an exercise program to help prevent reoccurrence of symptoms.

References:

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- 4 Vella, A. Circulator boot therapy alters the natural history of ischemic limb ulceration. *Vascular Medicine* 2000; **5**: 21-25.
- 5 Filip JR. Treatment of End-Stage "Trash Feet" with the end-diastolic Pneumatic Boot. *Angiology* 2008; **59**: 214-219