

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 of the feet. There is a growing number of clinicians actively using the technique as the first treatment of choice. Hundreds of limbs have been saved and many lives saved. It has FDA listing in the USA and TPP listing in Canada.

Discussion

Documented evidence^{1, 2, 3, 4} 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 cases⁴. 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 cardiosynchronous 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 clinical data^{3, 4} is available that documents the 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 and after treatment.

It is concluded therefore that effectiveness is positively established with sufficient documented strength of

evidence for its listed indications at a LEVEL OF EVIDENCE “B”. 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. The Circulator Boot should be used as a clinical treatment for cases of vascular insufficiency.
2. Compression bandages, wound management therapy and exercise should be used first, and continued as long as there is positive healing.
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.
4. The Circulator Boot should be considered prior to any surgical procedures including angioplasty, resection and amputation.

References:

- 1 Koch CA. External leg compression in the treatment of vascular disease. *Angiology* 1997; **48**: S3-15.
- 2 Dillon RS. Patient Assessment and examples of a method of treatment. Use of the circulator boot in peripheral vascular disease. *Angiology* 1997; **48**: S35-58.
- 3 Dillon RS. Fifteen years of experience in treating 2177 episodes of foot and leg lesions with the circulator boot. Results of treatment with the circulator boot. *Angiology* 1997; **48**: S17-34.
- 4 Vella, A. Circulator boot therapy alters the natural history of ischemic limb ulceration. *Vascular Medicine* 2000; **5**: 21-25.