

Facts & Figures

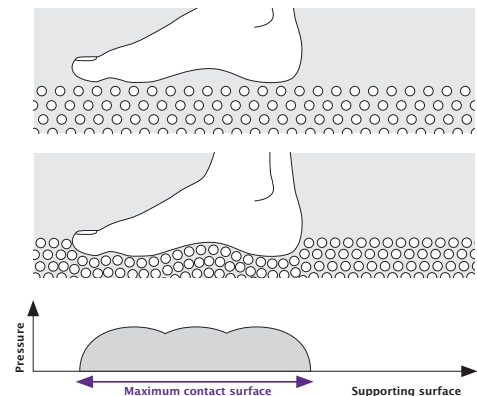
Treatment Comparison and Study Results



Product information

Total contact offloading with Vacuum Technology

- Vacuum cushion, filled with small styrofoam beads, mould perfectly to individual patient anatomy.
- When air is removed from the cushion it becomes rigid; providing a total contact surface which effectively supports the foot while relieving pressure.
- Re-adjustment can be performed as often as necessary.
- Pressure is evenly distributed through the maximum contact surface. Only fixation of the beads, without applying pressure on the limb.



The Strap Lock For Safety and Compliance

- VACOCast/VACOped/VACOpedes Diabetic can be made non-removable by using the strap lock*
- To aid concordance with treatment
- Dressings can be accessed and product can be relocated



* Optional, not in standard set

Guidelines

VACOCast Diabetic and VACOped Diabetic fulfill the IWGDF Guidelines as non-removable and removable knee high devices!

Bus et al. Guidelines on offloading foot ulcers in persons with diabetes (IWGDF 2019 update). Diab Metab Res Rev. 2020. e3274

Guidelines of the International Working Group on the Diabetic Foot (IWGDF)

Recommendation for healing a neuropathic plantar forefoot or midfoot ulcer in a person with diabetes:

Recommendation 1:

- „(...) use a **non-removable knee-high offloading device** with an appropriate foot-device interface as the first-choice of offloading treatment to promote healing of the ulcer. (GRADE strength of recommendation: Strong; Quality of evidence: High)“
- „(...), **use either a total contact cast or non-removable knee-high walker**, with the choice dependent on the resources available, technician skills, patient preferences and extent of foot deformity present. (Strong; Moderate)“

Recommendation 2:

„(...) for whom a **non-removable knee-high offloading device is contraindicated or not tolerated**, consider using a removable knee-high offloading device with an appropriate

foot-device interface as the second-choice of offloading treatment to promote healing of the ulcer. Additionally, encourage the patient to consistently wear the device (Weak; Low).“

“The **TCC had been considered for decades the gold standard** offloading intervention to heal neuropathic plantar ulcer. Our previous guidelines **broadened the recommendation to a non-removable offloading device**, to include both, a TCC and a pre-fabricated removable knee-high walker rendered



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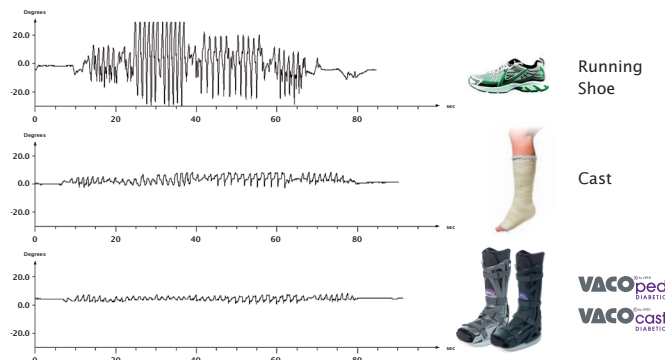
Studies & Measurements

Vacuum Offloading Orthoses – stable as a cast

Mitternacht J, Schaff P. Biomechanical study. 1994 Aug/Sept.

The diagram shows the amplitude of flexion/extension in the ankle joint while stair climbing (electronic goniometer)

* The biomechanical study was done with VACOped. The results can be transferred to VACOped Diabetic and VACOcst Diabetic as the product essentially correspond in structure.



High healing rates and excellent patient satisfaction with VACOcst Diabetic

Bowen G, Spruce P. Evaluating a removable knee high cast walker within the diabetic foot pathway. The Diabetic Foot Journal. 2019; 22(3): 52-9

Objective

Evaluation of a removable cast walker in the diabetic foot pathway to determine the potential outcomes and costs in wounds where a non-removable device was contraindicated, or not acceptable to the patient.

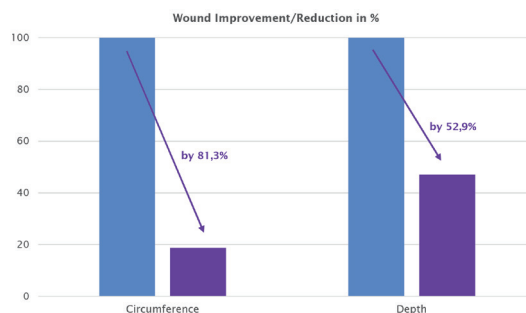
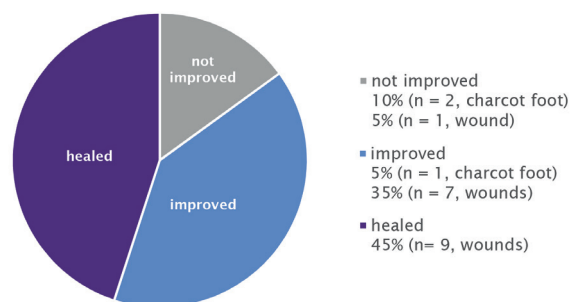
Patients and method

- 20 patients with diabetes (17 with foot ulcers, 3 with charcot foot)
- Treatment in VACOcst Diabetic for up to 8 weeks

Results

- 16 out of 17 ulcers improved or healed within 8 weeks!
- Reduction of wound circumference by 81,3%
- Reduction of wound depth by 57,9 %

Conclusion: Superior Outcome in the Treatment of the Diabetic Foot Syndrome with VACOcst Diabetic.



Vacuum Offloading Orthosis shows most homogenous Distribution of Forces compared to TCC and other Devices

Götz J et al. Off-loading strategies in diabetic foot syndrome-evaluation of different devices. Int Orthop. 2017 Feb;41(2):239-246

Objective

Assessment of different offloading devices compared to walking in barefoot condition and in normal shoes.

Patients and method

- Pedobarographic examination was performed while walking: 20 patients with Diabetes and peripheral neuropathy, 10 healthy probands
- Devices tested: Post-op shoe "Hannover", Fior&Gentz o Total Contact Cast (TCC), Aircast Diabetic Pneumatic Walker o Standard shoe "Cascadia 4", Brooks, VACOped Diabetic (former VACOped Diabetic), barefoot

Results

- "The most **effective reduction of force** was achieved by **TCC (75%) and VACOped (64,3%)** with the VACOped resulting in the **most homogenous distribution** of forces all over the foot."
- "A customized device like the TCC is still the most proven offloading device. However, a removable cast walker being based on vacuum pads and a cushioning sole, provides better results concerning force distribution."

Conclusion: The comparison of offloading devices show the most homogenous distribution of forces over the foot with VACOped Diabetic.

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Studies & Measurements

Significant re-distribution of plantar pressure with Vacuum Offloading Orthoses

Nagel A, Rosenbaum D. Off-loading strategies in diabetic foot syndrome evaluation of different devices. Gait Posture. 2009 Jul; 30(1):11-5.

Objective

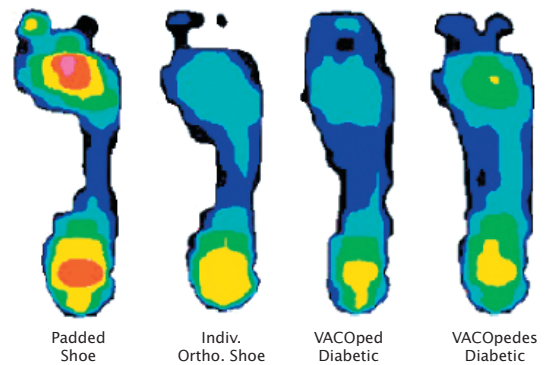
Investigation of the pressure-relieving effects of two vacuum orthoses (VACOped Diabetic, VACOpedes Diabetic) in patients with diabetes mellitus.

Patients and method

- 20 patients with diabetes mellitus with plantar callosities, but no ulceration.
- Plantar pressure distribution was measured with sensor insoles during walking in two different VACO-orthoses, a postoperative shoe and a common "Health Shoe".

Results

- Significant decrease of the the maximum force & peak pressures under the rearfoot and forefoot with VACOped Diabetic/VACOpedes Diabetic
- Contact area increased in the midfoot with the vacuum orthoses



Conclusion: Using VACOped/VACOpedes Diabetic significantly benefited re-distribution of plantar pressure and the roll-over process.

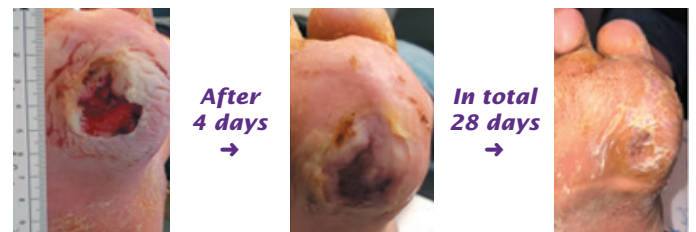
VACOcast Diabetic – accelerated ulcer healing

Cole W. Offloading diabetic foot ulcers with the next generation of pressure relief. W. Cole Today's Foot Clinic. 2020 Feb.

Case Study 1

VACOcast Diabetic applied (with lock). Ulcer healed within 28 days.

- 48 year old male, 6 month history of neuropathic plantar ulcer at 1st metatarsal head
- Patient had tried and failed multiple advanced wound care
- TCC was removed after discomfort & pain, then application of VACOcast Diabetic



Case Study 2

VACOcast Diabetic applied (with lock). Ulcer healed after 6 weeks.

- 45 year old female, with a surgical wound dehiscence of plantar left midfoot for 9 weeks
- Patient had tried and failed several advanced wound therapies with TCC
- The patient was transitioned into the VACOcast Diabetic locking boot due to complaints of leg cramping in the TCC

