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Test persons:	Case studies with 2 exemplary cases

## Offloading Diabetic Foot Ulcers With the Next Generation of Pressure Relief

### Objectives:

Effective offloading of lower extremity ulcers can mitigate one of the direst consequences of diabetes. The authors take a look at the future of offloading using an innovative device (VACOCast Diabetic, OPED).

### Facts:

- Diabetic patients have a 15–25% lifetime incidence of foot ulcers
- Approximately 20% of hospitalizations among the diabetic population are due to DFU, and 65% of patients will have a recurrence within 5 years
- Estimated up to 85% of all non-traumatic lower extremity amputations are a direct result of DFUs
- The current standard: adequate wound bed preparation, appropriate debridement, application of specialized dressings and **offloading which is of paramount importance in their treatment.**

### Offloading:

- Plantar foot ulcers are a direct result of **increased pressure** in the presence of neuropathy
- For successful wound healing, **repetitive stresses must be eliminated and plantar pressures must be decreased**
- These goals can be achieved through: bed rest, crutches, wheelchairs, roll-a-bout scooters, walkers, total contact casts (TCC), **removable cast walkers**, custom splints, Charcot restraint orthotic walkers (CROW), extra-depth shoes, half-shoes, surgical shoes, felted foam, and bulky bandages.
- Most effective offloading is achieved when **forces are spread over a wide area** of contact while ensuring compliance
- TCC is the most validated and efficient offloading device. Why?
  - **eliminating ankle joint motion.** By prohibiting plantarflexion, force is reduced in the forefoot and midfoot, and weight is transferred to the lower leg.
  - Due to conical shape of the tibial segment of the lower extremity, **weight is transferred to the hard cast.**
  - TCCs **mold to the leg**, helping to decrease edema
  - TCCs are cumbersome, so **less action**, which can cause the patient to take fewer steps a day, thus reducing repetitive stresses
  - **Forced patient compliance.** Patients cannot easily remove the device on their own, which ensures that weight and pressure are adequately controlled

### Is TCC the Gold Standard?

- **IWGDF Guidelines** recommend a non-removable, knee-high offloading device
- A retrospective analysis of the U.S. Wound Registry found that TCC is not in common use:
  - Only 2.2% (4866) of the 221,192 plantar ulcers registered were offloaded. Of those only 16% (778) received a TCC; 36.8% (1790) were simply placed in a surgical shoe. Significantly more amputations

in the non-TCC-treated patients. Only 61% of the clinics participating in the registry used TCC, and of those, only 3.7% of patients with a “TCC-eligible” wound seen in those clinics received a TCC

- Common **concerns** regarding TCC: **expensive, messy, takes too much time, or has too great a risk for complications, application difficult**
- TCCs **contraindicated**: osteomyelitis or acute wound infection. Adequate perfusion is a must. **Weekly cast changes** are the standard of care; therefore, patients should be **compliant with appointments**.
- Studies of Fleischli and colleagues show that **prefabricated removable cast walkers (RCW) are as effective or more effective than the TCC at reducing plantar pressures**.
- Lavery and colleagues found that **TCC and Walker measured significantly lower mean peak pressures** (metatarsal heads, great toes) compared to different other offloading devices
- **Advantages** of Removable cast walkers:
  - **Allow wound access** for dressing changes
  - Patients may also remove the cast walkers to sleep and shower, reducing the impingement on their activities of daily living
- **Disadvantage**: Compliance: Patients remove and not replace the RCW.
- TCC allows “forced compliance”
- Armstrong and colleagues found significant differences in healing and time to heal in favor of TCC compared to RCW and half shoe linked to compliance (wearing the device)

#### VACOCast Diabetic: Best of both worlds

- Offloads forefoot and midfoot ulcers with the effectiveness of a TCC
- Rocker sole allows more normal gait pattern
- Bead-filled insert that re-molds under a vacuum at each fitting
- Comes with two washable low-friction wicking synthetic velour liners that can be easily exchanged for increased hygiene
- Toe cover to prevent debris from entering the boot
- Added foam bed layer allows for increased shock absorption
- Locking mechanism that provides forced compliance
- Excellent results in CIME Studie UK: Over 8 weeks 85% of patients either healed or improved. No device related injuries were reported and the device was highly rated by patients for comfort, safety, stability, and the ability to ambulate.

#### Cases:

- **Case 1**

48 year old male, 6 month history of neuropathic plantar ulcer at 1<sup>st</sup> metatarsal head  
Patient had tried and failed multiple advanced wound care  
TCC was removed after discomfort & pain  
VACOCast Diabetic applied (with Lock). Ulcer healed within 28 days.



- **Case 2:**

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 and TCC  
 The patient was transitioned into the VACOcast Diabetic locking boot due to complaints of leg cramping in the TCC  
 VACOcast Diabetic applied (with Lock). Ulcer healed after 6 weeks.



- **Case 3 (unpublished):**

56 year old male, 7 weeks history of non-healing ulcer of the right lateral plantar foot  
 Previous therapy: surgical shoe  
 VACOcast Diabetic applied (with Lock). Ulcer healed after 5 weeks



- **Case 4 (unpublished):**

62 year old female with a neuropathic ulcer of the left plantar heel  
 Previous treatments include surgical I&D of abscess with CTP application  
 VACOcast Diabetic applied (with Lock). Ulcer healed after 7 weeks.



**Conclusion:**

- Numerous reasons cause wound care clinicians to be unwilling to implement TCC therapy into their practice e.g. dressing changes. Removable cast walkers permit access to the wound for more frequent evaluations and bandage changes, but patients tend to not be fully compliant in their use. The lack of forced compliance remains the top reason healing rates for RCW are less than seen in TCC.

**The OPED VACOcast Diabetic locking cast boot may be the answer to bridging this gap by providing the ease of use of a RCW, but the benefit of forced compliance of a Total Contact Cast**